

PD-ABB-306

67244

Prepared for

Office of Population
Bureau for Science and Technology
Agency for International Development
Washington, D.C.
Under Contract No. DPE-3024-Z-00-8078-00
Project No. 936-3024

**EVALUATION OF THE NATURAL
FAMILY PLANNING PROJECT**
Project No. 936-3040

by

Judith Rooks
John France
Marianne Lown
Janith Williams

Fieldwork
January 5 - 26, 1990

Edited and Produced by

Population Technical Assistance Project
DUAL & Associates, Inc. and International Science
and Technology Institute, Inc.
1601 North Kent Street, Suite 1014
Arlington, Virginia 22209
Phone: (703) 243-8666
Telex: 271837 ISTI UR
FAX: (703) 358-9271

Report No. 89-055-107
Published July 17, 1990

Table of Contents

Table of Contents	i
Glossary	v
Executive Summary	vii
Part I Evaluation of the Natural Family Planning Project	
1. Introduction and Background	1
1.1 Purpose of the Project	1
1.2 The Evaluation	1
1.3 Scope and Complexity of the Project	2
1.4 The Context: Working in NFP	5
1.5 The Institute's Role in A.I.D.'s Overall Support of NFP	6
2. Project Administration	11
2.1 Initial Administration of the Institute	11
2.2 Present Administrative Structure	12
2.3 The Technical Advisory Group	13
2.4 The Establishment of Project Priorities	14
2.5 Project Review Process	14
2.6 Institute Staff	15
2.7 GU's Administration of the Cooperative Agreement	16
2.8 Institute Relationships with Related Organizations	16
2.9 A.I.D.'s Monitoring of the Project	18
3. Project Funding	19
3.1 Funding Levels	19
3.2 Expenditures by Organization	19
3.3 Expenditures by Project Element	19
3.4 Expenditures by Geographic Region	22
3.5 Adequacy of Funding	24
4. Research	27
4.1 The Establishment of Research Priorities	27
4.2 Constraints on Research	28
4.3 The Need to Distinguish between Program Evaluation, Operations Research, and More Rigorous Kinds of Research	29
4.4 Biomedical Research	29
4.5 Field ("Clinical") Trials	32
4.6 Operations Research	34
4.7 Social Science Research	36
5. Efforts to Support, Expand, and Strengthen NFP and LAM in LDCs	41
5.1 Overview	41
5.2 Activities Designed to Influence Policymakers	41
5.3 Efforts to Promote NFP, LAM, and Fertility Awareness among Multimethod Family Planning Programs and Child Survival Programs	42

5.4	Training NFP Instructors	44
5.5	Innovative IEC Outreach Activities	45
5.6	Improving the Management of NFP Service Delivery Programs	46
5.7	Increasing the Number of People Working in NFP and LAM	47
5.8	Maintaining a Resource Center	49
6.	Other Project Activities	51
6.1	Efforts to Build a Consensus within the NFP Community	51
6.2	Establishment of a Dialogue between NFP and Other Family Planning Groups	51
6.3	Dissemination of Research Findings and Other Institute Products	52
Part II	The Potential Contribution of NFP, LAM, and Fertility Awareness Education to A.I.D. Population Assistance Goals	
7.	The Potential Contribution of NFP, LAM, and Fertility Awareness Education to A.I.D. Population Assistance Goals	53
7.1	NFP, LAM, and Fertility Awareness Education in the Context of A.I.D. Population Assistance Goals	53
7.2	Profile of Women Who Use NFP and LAM	54
7.3	Service and Cost Considerations	56
7.4	Health Advantages and Risks	57
Part III	Recommendations	
8.	Recommendations	59
8.1	Recommendations for the Remainder of the Current Project	59
8.2	Recommendations for a Follow-On Project	61

List of Tables

Table 1	A.I.D. Office of Population Centrally Funded Support for Natural Family and Breastfeeding	7
Table 2	Utilization of Funds by Fiscal Year, by Each Organizational Component of the Institute, by other U.S. Subcontractors, and by LDC Subcontractors	20
Table 3	Utilization of Funds, by Project Element	21
Table 4	Utilization of Funds, by Project Element and Type of Organization	22
Table 5	Utilization of Funds for Breastfeeding and for Natural Family Planning and Fertility Awareness	23
Table 6	Utilization of Funds, by Geographic Region	24
Table 7	Institute Projects and Activities, by Implementing Agency	48

List of Figures

Figure 1	Original Institute Structure	11
Figure 2	Present Institute Structure	13

List of Appendices

Appendix A	Evaluation Scope of Work
Appendix B	Members and Meetings of the Technical Advisory Group
Appendix C	Institute Staff
Appendix D	Current or Recently Completed Biomedical Research Projects
Appendix E	Institute Publications
Appendix F	List of Persons Contacted

Glossary

A.I.D.	U.S. Agency for International Development
AIDS	Acquired immune deficiency syndrome
CA	Cooperating Agency
CM-BBT	Cervical mucus-basal body temperature method of natural family planning
CONRAD	Contraceptive Research and Development Project
CTO	Cognizant Technical Officer
DHS	Demographic and Health Survey
FEMAP	Federacion Mexicana de Asociaciones Privados de Planificacion Familiar
FHI	Family Health International
GU	Georgetown University
HIV	Human immunodeficiency virus
IEC	Information, education, and communication
IFFLP	International Federation of Family Life Promotion
IGAB	Interagency Group for Action on Breastfeeding
IPPF	International Planned Parenthood Federation
IRD	Institute for Resource Development, Inc. (formerly Westinghouse)
KCS	Kenya Catholic Secretariat
LAM	Lactational amenorrhea method (of contraception)
LARFPC	Los Angeles Regional Family Planning Council
LDC	Less developed country
MOH	Ministry of Health
MWRA	Married women of reproductive age
NICHD	National Institutes of Child Health and Human Development
NIH	National Institutes of Health
NP	Nurse practitioner

PAHO	Pan American Health Organization
PITT	University of Pittsburgh Graduate School of Public Health
POPTECH	Population Technical Assistance Project
STD	Sexually transmitted disease
SIDA	Swedish International Development Authority
TAG	Technical Advisory Group
TOT	Training of trainers
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Emergency Fund
WHO	World Health Organization

Executive Summary

Introduction

The Natural Family Planning Project is being implemented by the Institute for International Studies in Natural Family Planning through a cooperative agreement between the U. S. Agency for International Development (A.I.D.) Office of Population and Georgetown University. The project originally covered the period September 1985 to September 1990; it was later extended through September 1991. The Institute includes three organizational components: Georgetown University School of Medicine (GU), the Los Angeles Regional Family Planning Council (LARFPC), and the University of Pittsburgh Graduate School of Public Health (PITT). A fourth organization, the International Federation of Family Life Promotion (IFFLP), participates through a large subagreement.

The project was designed to improve the knowledge, availability, acceptability, and effectiveness of natural family planning (NFP) in less developed countries (LDC). NFP was defined to include all methods of contraception that rely on periodic abstinence and/or breastfeeding; however, breastfeeding did not become a major emphasis until the third year of the project.

Project Implementation

The project is being implemented by a new institutional entity and works within a difficult environment. NFP is a relatively new field, with few experts, weak institutions, and limited absorptive capacity. Some factions within the NFP community believe that the use of other contraceptive methods is morally wrong. There is also a certain amount of competition and animosity between groups which promote different methods for practicing NFP. Although located in a Catholic university, the Georgetown University School of Medicine had limited previous experience in NFP; it took a while for it to develop credibility in the field. During the first year or so of the project, the Institute had to expend considerable time and energy dealing with the political aspects of NFP. It was necessary to do a considerable amount of groundwork, even to develop a consensus with regard to the definitions of terms, before the Institute could begin to make appreciable progress. The Institute has also had to deal with some prejudice, even hostility, against NFP on the part of many persons who work in mainstream family planning service delivery organizations. Despite these constraints, the project has made considerable progress in several areas.

Synthesis and Dissemination of Research Findings

The Institute has made an important contribution by summarizing the existing scientific knowledge regarding NFP and lactational amenorrhea (LAM) as a method of contraception, and presenting it in an objective, non-promotional manner which addresses the concerns and interests of policymakers and professionals. The Institute has disseminated this information through means designed to attract the attention and respect of U.S., international, and LDC maternal and child health and family planning opinion leaders. It has been important that the synthesis of research findings has come from an institution based in a respected medical school.

Development of Consensus within the NFP Community

The Institute has also helped to develop greater consensus within the NFP community. It has added its weight to the moderate side of divisive issues, and has provided and guided processes through which people with different opinions can work together constructively. With less internal conflict, the NFP community has been able to put more of its energy into moving forward.

Improvement of NFP Service Provision

About half of the Institute's resources are used for activities related to improving services. Since NFP and LAM are entirely based on behavior rather than on the use of a product, methods to induce behavioral change are at the center of the effort. Approximately 30 percent of the project budget goes to support efforts related to information, education, and communication (IEC) and training. The Institute's IEC and training staff at LARFPC and GU are experienced and highly skilled and their work is of a very high quality. Three regional training of trainers (TOT) courses have enhanced the skills of 59 individuals who were already functioning as NFP instructors or multimethod family planning trainers in Africa, Latin America, and Asia. The Institute has based some of its other activities around this core of well-trained NFP instructors. At least 1,200 additional NFP instructors have been trained through second and third generation courses. The Institute's other major training achievement has been the production of the publication, *Guide for Natural Family Planning Trainers*.

Most of these training efforts have focused on increasing the quantity and quality of the NFP instruction that is available through NFP-only service providers, most of which function through small projects associated with the Roman Catholic Church. So far the Institute has done relatively little work related to incorporating NFP into multimethod family planning services. The limited experience to date suggests that it is better to use a person who is already committed to NFP to provide that service, and to train multimethod family planning workers to counsel and refer women to an NFP specialist. The Institute is planning a 1991 meeting on how to integrate NFP programs into ongoing multimethod family planning service delivery programs.

The Institute is trying several promising innovative approaches to IEC and outreach which are reaching beyond both the church and the health care system. Each of these activities includes an operations research component; by the end of the project (September 1991) it should be possible to assess the effectiveness of these approaches, which include a project to reach young women enrolled in home economics courses in the Cote d'Ivoire and a project which is using mass media and community events to reach women in Peru.

The Institute has tried several ways to help NFP programs improve their management and administration. It does not seem, however, to have a carefully developed strategy for this effort, and there is no evidence of significant success in this area. In addition, the Institute (through IFFLP) provides program support for a limited number of NFP-only programs in eight African countries.

Breastfeeding/LAM Efforts

Although the Institute's emphasis on breastfeeding did not start until early 1988, it has become a significant part of the project's work. The Institute provides

secretariat functions for the Interagency Group for Action on Breastfeeding (IGAB), an ad hoc coalition of technical staff with interest in and responsibility for breastfeeding activities at UNICEF, WHO, SIDA, and A.I.D. With this support, the IGAB has convened several important technical meetings, each of which resulted in an influential report, and has become an effective force within the international health policy arena. The Institute is the only component of the IGAB with special expertise and interest in the contraceptive (as compared to the child health) benefits of breastfeeding. The Institute is trying several approaches to teach health workers how to encourage and support breastfeeding and the lactational amenorrhea method of contraception during the six months immediately after a woman gives birth. These efforts include a project to develop a breastfeeding curriculum for schools of nursing in Latin America and studies in three Latin American countries which will assess the impact of a variety of breastfeeding interventions on breastfeeding practices, maternal and infant health and, in at least one case, pregnancy rates during the first six post-partum months. Another important effort is an IEC project to promote optimal breastfeeding practices for child spacing and child survival among the Indian population of Cuzco, Peru. This project coordinates radio programs with community activities and breastfeeding education for health professionals and policymakers.

Research

Almost half of the Institute's efforts have been related to research; however, since most of the research projects are not yet completed, the outcomes of this work are not really known. The Institute is conducting important basic research on the physiology and endocrinology of a woman's fertile period and has made progress towards identifying biologic chemical indicators which could be used as the basis for an accurate test kit with which women could determine their fertile days at home. Such a kit might make NFP an attractive option for millions of women in Western countries, and increased use of the method in those countries might make the method more attractive to couples in LDCs. The Institute is also conducting a study which should definitively refute concerns that NFP may result in conception of defective fetuses due to "aging gametes." The long-term purpose of most of the Institute's biomedical breastfeeding studies is to determine whether women with lactational amenorrhea can use NFP methods (i.e., the measurement of basal body temperature and observation of cervical mucus), or possibly some simple test of accessible body fluids, to predict and/or detect their first post-partum ovulation. Findings to date, however, have not been very encouraging.

A variety of operations research projects will assess the effectiveness of various efforts to promote breastfeeding (in several Latin American countries); compare the quality, acceptability and cost-effectiveness of group teaching to that of individual NFP instruction (in Mauritius); and explore the feasibility of integrating NFP into a multimethod family planning program (in the Philippines). Through its component at the University of Pittsburgh, the Institute has supported productive research that is based on a large and unique computerized NFP data base. Although analysis of these data have yielded important results, the biostatistician responsible for the work is no longer associated with the Institute and he has not published these findings yet. In addition to the work already done, the data could be used to calculate the probability of pregnancy associated with intercourse on specific days of the menstrual cycle and to define, for various sets of NFP rules, the number of days of abstinence required to reduce the pregnancy rate by a specified amount. This data analysis program also makes it possible to profile a local NFP program rapidly and at a reasonable cost; this capacity could be used in future program evaluation and operations research.

The Institute's social science arm (at PITT) has focused mainly on secondary analysis of existing data, mostly from surveys that measure fertility, contraception, and indicators of maternal and child health in specific LDCs. Although surveys conducted before 1987 only asked about "rhythm" (not other types of NFP) and did not collect enough information on breastfeeding to allow for calculation of the use of LAM, the Institute has arranged for more specific questions to be asked during future surveys. This work has been slow, but it appears to be cost-effective, productive, and important. The reports being prepared at PITT are well-written, interesting, and should result in influential publications. PITT has also produced a thorough and well-written review of published and unpublished behavioral research on NFP from throughout the world, and convened a meeting of experts to discuss psychosocial issues in NFP.

The Institute has not given sufficient attention to two particularly important areas of research: 1) field (or "clinical") trials to measure the rates of effectiveness and continuation associated with various NFP methods, including calendar rhythm, and with possible improvements in those methods, especially changes which might reduce the number of days that a couple using the method has to abstain from sexual intercourse; and 2) studies of the human behavior involved in contracepting through periodic abstinence. Both of these kinds of research were included in A.I.D.'s original project paper, and were either specified or alluded to in the cooperative agreement between A.I.D. and GU. Nevertheless, there is considerable interest in learning whether the effectiveness and acceptability of NFP can be improved by modifying the rules to reduce the required length of abstinence. Although the Institute has undertaken one such study, it was conceptualized as an operations research project and has not been given the attention and support necessary to assure the rigor needed in a clinical trial. In addition, the Institute has started only one actual behavioral research project -- a prospective study of psychosocial factors that influence the choice, continuation, and successful use of NFP among clients of a program in Mauritius.

Project Administration

Although GU is the prime recipient in the cooperative agreement, this project was originally thought of as a consortium of three relatively equal members. The GU component, however, has assumed increasing control and now functions as though it were the Institute; LARFPC and PITT are essentially functioning as subcontractors. This change, along with administrative problems at GU, has resulted in considerable stress among the Institute's three components.

Subsequent to an independent management review, the administrative structure of the Institute was reorganized in July 1989. Although the new structure appears to be an improvement, its long-term success will require continued intensive involvement of the project's principal investigator (who as chairman of GU's Department of Obstetrics and Gynecology has major clinical, teaching, and research responsibilities), and collaboration among the directors of the four reorganized divisions headquartered at GU.

The Institute has been slow to establish a strategy. Individual proposals have been judged on their intrinsic qualities but not in regards to their potential contribution to a set of clear, prioritized objectives. Decisions to pursue specific projects were influenced by various factors, including the skills and pre-existing personal interests of senior staff. The lack of field studies and behavioral research may be related to the lack of epidemiologic and behavioral science skills among the original staff of

the Institute. At the same time, the Institute has an excellent staff, some of whom are well-known and highly respected in their fields.

A.I.D. has monitored and, in fact, served as mentor to this project to an unusual extent; A.I.D.'s interventions have been constructive. The Institute has made efforts to reach out to the other A.I.D. Office of Population Cooperating Agencies (CA), and has provided them with useful information on NFP and LAM. More, however, needs to be done in this regard.

The project will use somewhat more than \$15 million over six years. A little less than one-third of the project funds will be used for work related to breastfeeding, with that amount almost equally divided between lactational amenorrhea as a method of contraception and other breastfeeding work. The project has resulted in a net increase in A.I.D. Office of Population funds for NFP. Nearly 70 percent of such support now comes through this project; other A.I.D. CAs are now spending less on NFP.

Major Recommendations

The Institute should broaden its view of its mission, in particular, by focusing on calendar rhythm as well as on modern NFP methods; by focusing on fertility awareness as a body of information and skills that are of use to most women, not only those who are practicing NFP; and by investigating the potential for interest in NFP among cultural groups that have not been previously involved.

A.I.D. should fund a second NFP project when the current one ends. Because of the diverse expertise required for this project, it may be necessary to involve at least two, and possibly three or more, organizations. The legal relationships between the organizations which agree to work on such a project should be subcontracts between the lead organization and the other major collaborators. Although IFFLP should not be considered as an inherent component of the project, its participation is essential and should be sought. The project should be implemented through two major divisions, one for LAM and one for NFP and fertility awareness. It should be led by a project director whose primary work is the overall direction of the project. Sixty percent of the project's programmable resources should be devoted to work related to NFP and fertility awareness; 40 percent should be devoted to work related to LAM. NFP project money should emphasize the contraceptive effects of breastfeeding.

Part I

Evaluation of the Natural Family Planning Project

1. Introduction and Background

The U.S. Agency for International Development (A.I.D.) Office of Population's Natural Family Planning Project is being implemented by the Institute for International Studies in Natural Family Planning, through a cooperative agreement between A.I.D. and Georgetown University (GU). The Institute includes three organizational components: Georgetown University School of Medicine, which is the major recipient; the Los Angeles Regional Family Planning Council (LARFPC); and the University of Pittsburgh Graduate School of Public Health (PITT). The original cooperative agreement was for a five-year project; it began on September 12, 1985, and was scheduled to be completed in September of 1990. The project was been extended for one year and is now scheduled to end on September 30, 1991.

1.1 Purpose of the Project

The project was designed to improve the knowledge, availability, acceptability and effectiveness of natural family planning (NFP) in less developed countries (LDC). NFP is defined in this context to include all methods of contraception that rely on periodic abstinence and/or breastfeeding. The project is intended to contribute to the joint aims of A.I.D.'s population assistance program, which are 1) to enhance the freedom of individuals in LDCs to choose voluntarily the number and spacing of their children, and 2) to encourage population growth which is consistent with the growth of economic resources and productivity. A.I.D. initiated this project in order to create the capability to meet LDC needs for NFP -- not to encourage the use of this method in preference to others, but to inform people about it, make it available, and support and strengthen organizations that provide NFP services.

1.2 The Evaluation

1.2.1 Evaluation Team Members

The evaluation team consisted of three technical experts and an editor who served as report coordinator. The technical members included two Americans and a New Zealander; there was no LDC participation. The team leader, Judith Rooks, CNM, MS, MPH, is a nurse-midwife and epidemiologist with U.S. and LDC experience in breastfeeding and multimethod family planning research and training; she has no specific expertise in NFP. John France, PhD, DSc, is a biochemist who has specialized in reproductive endocrinology; he has contributed to the biomedical research base for NFP and has had a long involvement in the organization of the delivery of NFP services in New Zealand. Janith Williams, BSN, is a nurse practitioner who has taught NFP and has contributed to training, materials development, and evaluation of NFP in multimethod family planning programs and NFP-only services. It should be noted that Ms. Williams is a consultant to LARFPC in NFP, although she has not served as a consultant to LARFPC's Institute-related work. The report coordinator was Marianne Lown, a member of the Population Technical Assistance Project (POPTECH) staff.

1.2.2 Evaluation Scope of Work

The scope of work for this midterm evaluation called for the team to examine 1) project work to date that has been undertaken in response to the project's stated purposes and priorities, and 2) the project implementation process. The evaluation team was instructed to focus less on project accomplishments and more on both past and future project priorities and processes. (See Appendix A for the complete scope of work.)

In addition to the written scope of work, the team decided, with agreement from the A.I.D. Cognizant Technical Officer (CTO) for the project, to attempt to look at the achievements of the project within the context of the needs of the entire field, i.e., not to focus only on what the Institute has done, but on what it has done in relationship to what it might have done and what is needed.

1.2.3 Evaluation Methodology

The evaluation was conducted in Washington, D.C., Los Angeles, and Pittsburgh between January 5 and January 26, 1990. The evaluation team was briefed by all three A.I.D. officials who have served as CTO for the project. The team interviewed staff of all three organizational components of the project (GU, LARFPC, and PITT), the International Federation of Family Life Promotion (IFFLP), and local NFP leaders in Washington, D.C., Los Angeles, and Pittsburgh. Telephone interviews were conducted with key personnel from a variety of other organizations involved in international family planning program assistance or contraceptive development research. However, the evaluation team did not travel outside of the United States and thus was not able to visit any of the LDC projects that have been supported through the Institute. In order to learn more about the Institute's processes and the quality of its work, the evaluation team selected a small number of discrete projects to look at in greater depth from their inception through their development and implementation.

1.3 Scope and Complexity of the Project

1.3.1 Institute Structure

From the start, the Institute was designed as a complex enterprise requiring three geographically separated units, each housed in its own organization, to collaborate in achieving a very large scope of work. Shortly after the project began, the Institute entered into a major subagreement with IFFLP, thus increasing the actual number of functional components to four.

Georgetown University. GU's role in the Institute's activities was intended to provide overall management and coordination of subprojects, to conduct the biomedical research component, and to undertake information, education, and communication (IEC) activities. To fulfill this role, it brought together a project staff that included the chairman of its Department of Obstetrics and Gynecology as the project's principal investigator; a project director with experience related to both NFP and multimethod family planning services in Latin America; an IEC specialist with related experience in the U.S., Africa, and the Caribbean; and a group leader for the biomedical component of the project.

Although GU's Department of Obstetrics and Gynecology had little previous involvement in NFP, it is a respected academic department of a prestigious private Roman Catholic university; as such, it commands respect in both Catholic and secular spheres of influence. GU's Department of Obstetrics and Gynecology works closely with its Department of Pediatrics and the GU-based Capital Area Milk Bank in breastfeeding promotion and research. It also has a long-term relationship with the Department of Community Medicine in doing work in biostatistics and epidemiology and with numerous other departments, as well as with the National Institutes of Health (NIH) and pharmaceutical companies in clinical research and trials.

GU provides potential access to graduate students (e.g., in nursing, nurse-midwifery, and epidemiology) and to patients. It has a collaborative relationship with and has given financial support to the Maryland/District of Columbia Natural Family Planning Providers organization, and its location in Washington, D.C., makes it convenient to A.I.D., many A.I.D. Office of Population Cooperating Agencies (CA), the NIH, and the Pan American Health Organization (PAHO).

Los Angeles Regional Family Planning Council. LARFPC's main roles in the Institute have been to provide a capability for training NFP teachers and to provide technical support to projects with a training component. LARFPC was established in 1968 for the purpose of managing the government-subsidized family planning service delivery program in Los Angeles County. It shares staff, space, and leadership with the California Family Planning Council. Between them, the two groups manage the federal- and state-supported family planning program for the entire state of California; that system provided 525,000 family planning visits to 240,000 clients last year. In addition, LARFPC has an ongoing program for training nurse practitioners (NP) and medical doctors (MD) in the delivery of family planning services; the training materials developed for its domestic training program have relevance for international work; and vice versa.

LARFPC functions through four units: Training and Education, Quality Assurance, Research, and Finance. The Training Unit provides primary family planning training to about 350 NPs and MDs and 350 community workers every year. In addition, it conducts a contraceptive update course for between 100 and 200 NPs and MDs, a course to prepare NFP instructors, and NFP refresher training. The Research Unit includes epidemiologists and has experience in conducting contraceptive clinical trials. The unit has conducted trials on the cervical cap and on a specific type of vaginal sponge. LARFPC has a close working relationship with several departments at the University of Southern California and the University of California at Los Angeles, including the latter's internationally respected program for lactation training and research.

LARFPC was well prepared for its role in the Institute through its involvement in providing NFP training and services to people in California. LARFPC has received grants from the U.S. Department of Health and Human Services specifically to provide NFP services to clients in Los Angeles. Since a large portion of the people LARFPC serves are Spanish speaking, most of the training aids it develops are produced in Spanish as well as English. Its clientele, though American, consists largely of relatively recent immigrants from LDCs.

LARFPC trained the NFP instructors who participated in the NFP use-effectiveness study which was conducted at Cedars Sinai Hospital in Los Angeles during the 1970s. LARFPC has assisted the National Coalition of American NFP leaders to conduct several international symposiums on NFP. In the current A.I.D.-funded project, LARFPC has focused on training activities and has provided on-site support to NFP organizations in LDCs. LARFPC's staff made more than 40 trips to LDCs during the first four and a half years of the project.

The School of Public Health at the University of Pittsburgh. PITT has had primary responsibility for the social science research component of the project and has contributed to the operations research component. Its major accomplishments have been to 1) carry out secondary analysis of survey data, 2) conduct evaluation and operations research studies, 3) provide the sophisticated data processing capability needed to support some biomedical studies, and (4) summarize the literature on the behavioral science aspects of NFP and conceptualize the needs and some potential strategies for future work in this area.

The Pittsburgh area has a strong network of NFP providers; PITT has worked with them and supported their efforts over a period of many years. A salient achievement of this collaboration has been the creation of a computerized data set that contains information from more than 16,000 NFP-user charts. Most of the women whose charts are included in this data set were using the cervical mucus-basal body temperature (CM-BBT) method, so it is often referred to as Pittsburgh's "CM-BBT" data set. A biostatistician at PITT created the data set and also the software which enables him to analyze these charts. It is a unique and valuable resource. (See section 4.6.3.)

PITT staff have had a long-standing interest in NFP. The PITT component is led by a sociologist who is an expert in health services evaluation and research, and who has

international as well as considerable domestic experience. He has other major administrative and academic responsibilities at the Graduate School of Public Health and is assigned to the NFP project at 35 percent of time. Another member of the PITT team is an anthropologist who speaks several languages and has had extensive international experience; he works on the project half time and is providing most of PITT's current contribution to operations research. The third member of the team is a demographer who is now giving 70 percent of his time to the project. In addition to demographic analysis, he has conducted an extensive review of the literature on the behavioral aspects of natural family planning. Although there is a social psychologist on the staff of the Graduate School of Public Health, she is not working on the NFP project and it is not her field of interest. No one with experience in the conduct of behavioral research related to sexuality and contraception is assigned to this project.

The International Federation for Family Life Promotion (IFFLP). Although the IFFLP is a subcontractor and not an actual component of the Institute, the level of resources devoted to it and the breadth of its workscope make it appropriate to describe its work here.

IFFLP was founded in 1974 as a non-governmental international organization through which local or national NFP organizations could collaborate to promote the use of natural methods of fertility regulation in countries throughout the world. It now has 135 member organizations in 80 different countries. Many of its members are Roman Catholic organizations, but it is becoming more ecumenical; two Muslim organizations have joined, and membership is open to secular organizations.

When the Institute began (September 1985), IFFLP was halfway through its own five-year contract with A.I.D. (August 1983 to July 1988). Because IFFLP was already active and well known in many LDCs, A.I.D. suggested that the Institute form a major subagreement with IFFLP in early 1986. IFFLP has been a major partner in the work of the Institute since that time.

The IFFLP worldwide network of members and contacts in 104 countries -- including 39 in Africa, 22 in the Americas, 24 in Asia/Oceania, and 19 in Europe -- has provided the Institute with many opportunities and resources to promote its work, especially in Africa. Although IFFLP has members in all regions of the world, its work for the Institute is focused in eight African countries where it is concentrating on improving the teaching, supervision, and management of NFP services provided through organizations largely affiliated with the Roman Catholic Church.

The Institute has also used IFFLP regional meetings and international congresses to disseminate the results and findings of its research and other work, and to identify potential partners for new projects. The Institute has provided a substantial amount of financial support for these meetings and congresses and has given numerous technical and scientific presentations at the congress sessions. Furthermore, because IFFLP is a major international natural family planning organization, its association with the project has helped to establish the Institute's considerable and essential credibility in the NFP community.

1.3.2 Project Scope of Work

The project paper and cooperative agreement call for 45 percent of project resources to be devoted to research, including biomedical research (20 percent), operations research (15 percent), and social science research (10 percent); 25 percent to be used for IEC and training; 20 percent for technical assistance; and 10 percent for other assistance, including commodity support, support for NFP services, international and national conferences, workshops and symposia, travel and study awards, and analysis of existing data.

The cooperative agreement laid out a fairly comprehensive set of needs and possible projects within each of the specified areas of work: it suggested 10 important questions which

could be addressed by biomedical research, 18 questions which could be addressed by operations research, 5 areas for social science research, and 7 targets for information, education, and communication activities. Instead of requiring specific work products, the cooperative agreement called for a Technical Advisory Group (TAG) to help the project establish priorities among many possibilities. GU proposed an organizational structure for the project that included the three separate institutions.

The cooperative agreement did, however, specify that, to the extent possible, the various project components should be programmed to work together, e.g., operations research to assess the impact of a training program provided for an NFP service delivery project. Thus, it was necessary for the three geographically separated organizations to conduct their own work in tandem with the other units and to collaborate on a large number of separate projects to be implemented in LDCs.

During the third year of the project, A.I.D. asked the Institute to increase its work in breastfeeding, an area which had been included but not emphasized in the original project paper and cooperative agreement. This new emphasis became possible when the current director of the Division for Breastfeeding joined the staff of the Institute in November of 1987. Shortly after her arrival, A.I.D. requested that the Institute begin to provide secretariat functions for the Interagency Group for Action on Breastfeeding (IGAB), an ad hoc coalition of technical staff with interest and responsibility for breastfeeding activities at UNICEF, WHO, SIDA, and A.I.D. The IGAB was formed in late 1985 and had already met two or three times, but had no staff support. The Institute has provided the secretariat functions for the IGAB since 1988, assisting the group to meet four times and to convene several technical meetings, including a meeting on definitions of breastfeeding, a meeting on health care practices related to breastfeeding, and a meeting to plan a conference on breastfeeding and working women. This emphasis on breastfeeding was given a further boost following the meeting convened in Bellagio, Italy, in August 1988,¹ which resulted in a consensus among experts that breastfeeding provides 98 percent protection from conception for at least the first six postpartum months so long as the woman remains amenorrheic and most of the baby's nourishment comes from its mother's milk. The Bellagio meeting helped create a broader and stronger interest in breastfeeding within the Office of Population at A.I.D.; shortly thereafter, A.I.D. asked the Institute to increase significantly its work in breastfeeding as a method of family planning.

In addition, although it is not an area with a detailed list of illustrative projects in the cooperative agreement, there is now a growing awareness, within the Institute and elsewhere, of the potential importance of fertility awareness (women's self-knowledge of how their bodies work with reference to the fertile and infertile phases of the menstrual cycle) as a base of information and skills which are needed by most women, not only those who choose to use natural family planning. Fertility awareness combined with abstinence during the fertile period is the essence of NFP; thus, proponents of NFP have been leaders in developing the science and methods of fertility awareness.

1.4 The Context: Working in NFP

Modern NFP is a relatively new field; few experts are available to serve as consultants, and most of the organizations that provide NFP services in LDCs are small, unsophisticated, and run by volunteers who can devote only a few hours each week to NFP. In

¹The Bellagio Consensus Meeting was sponsored by the Rockefeller Foundation, the WHO Human Reproduction Program, and Family Health International (FHI).

addition, there are no large NFP data bases, and few well-designed training materials and other program aids. The Institute had to do a lot of groundwork, even having to forge a consensus among members of the NFP community with regard to the definition of terms (see Section 6.1), before it could make progress.

Modern NFP has developed with considerable indirect and direct support from the Roman Catholic Church, and NFP providers in many countries depend on the support of local parishes. Many NFP providers are motivated by a deep belief in the moral correctness of NFP, and some believe that the use of other contraceptive methods is wrong. In contrast, the U.S. Congress requires that all A.I.D.-funded family planning projects and activities must give individuals access to services and information about a variety of family planning methods, either directly or through referral. This Congressional mandate was incorporated in the project's cooperative agreement through an amendment signed on June 30, 1986. This means that, for many projects, the Institute can only work with those components of the international NFP community that are willing to work with organizations that provide information on other kinds of contraception. The NFP community (those who use, teach, and support the provision of NFP services) contains people with a variety of views and concerns regarding the acceptability of other family planning methods. Some accept the idea of collaborating with individuals and institutions that are involved in multimethod family planning, and welcome it as an opportunity to reach more people with the benefits of NFP. However, such collaboration is unacceptable to some members of the NFP community.

In addition, different groups of people have been trying to refine and promote different methods to identify the fertile days within a woman's menstrual period. This has led to the development of subgroups of people who are strongly committed to one particular NFP "method" (i.e., rules for determining the fertile period and for practicing NFP)². In some cases these beliefs and loyalties are very intense, causing estrangements among factions within the NFP community.

1.5 The Institute's Role in A.I.D.'s Overall Support of NFP

Although the Institute was supposed to be an "umbrella" project (that is, its activities would encompass work in all aspects of NFP), A.I.D. did not intend for other Office of Population CAs to reduce their own efforts in the area of NFP. In addition, the project was meant to be a "pass-through" project, meaning that the Institute would subcontract much of the work. There has been some confusion, however, as to whether the Institute was intended only to stimulate, coordinate, and synergize the work of others, to support others to do the work, or to do the work itself. Nevertheless, the decision to create an "institute" implies an intention to develop a center of excellence in NFP. Although an institute may support work performed by other organizations, it must conduct some of the work in-house in order to develop and maintain the expertise necessary to assess and direct a program of subcontracted projects.

Table 1 documents the amount of A.I.D. Office of Population central funds used to support NFP efforts by A.I.D. CAs before and after this project began. Collection of this

²The modern, or scientific, NFP techniques include the basal body temperature method, the cervical mucus or Billings ovulation method, and the sympto-thermal method. The rhythm (calendar) method, although the most widely practiced approach used to identify the fertile and infertile days of the menstrual cycle, is not considered to be as scientific nor as reliable as the other techniques now available. Source: Spieler, J. and S. Thomas. "Demographic aspects of natural family planning." *International Journal of Gynecology and Obstetrics*. 1989. Supplement 1:133-144.

Table 1
A.I.D. Office of Population Centrally Funded Support for
Natural Family Planning and Breastfeeding

Cooperating Agency	Actual Expenditures		Obligations	
	FY85	FY86	FY87	FY88
Center for Development and Population Activities (CEDPA)	\$ -	\$ -	\$ 10,650	\$ 16,175
Center for Population and Family Health (Columbia University)	-	* 426,622	* 201,995	* 87,495
Committee on Population	-	300	10,000	10,000
Demographic Data for Development	15,000	-	-	-
Demographic and Health Surveys Institute for Resource Development	-	140,000	245,000	192,500
Development Associates	42,000	51,385	41,610	47,650
Family of the Americas Foundation	758,000	-	-	-
Family Health and Demographic Surveys Project	100,000	-	-	-
Family Health International (FHI)	-	616,206	445,056	325,000
Family Planning International Assistance	220,124	155,581	108,045	-
The Futures Group	96,307	-	-	-
The Futures Group, Options for Pop. Policy	-	-	80,000	11,000
The Futures Group, RAPID II	-	* 160,000	* 180,000	* 52,000

* Includes development and monitoring costs.

Table 1
A.I.D. Office of Population Centrally Funded Support for
Natural Family Planning and Breastfeeding

Cooperating Agency	Actual Expenditures		Obligations	
	FY85	FY86	FY87	FY88
Institute for International Studies in Natural Family Planning**	\$ -	* 1,568,398	* 2,000,087	* 3,291,810
Institute for Resource Development	-	4,100	3,300	-
International Federation for Family Life Promotion (IFFLP)	572,000	* 294,000	* 595,000	* -
International Science and Technology Institute	28,030	48,045	-	-
INTRAH	173,525	* 239,333	* 267,788	* 212,800
John Snow, Inc. (Enterprise Program)	-	-	49,815	7,500
Johns Hopkins University, Program for International Education in Gynecology and Obstetrics	153,767	213,262	150,000	150,000
Johns Hopkins/Population Communications Services (JHU/PCS)	103,072	100,021	113,900	199,600
Johns Hopkins Population Information Program (PIP)	45,000	31,508	86,510	84,510
Johns Hopkins University (School of Hygiene/PH, Pop Dynamics)	80,000	-	-	-

* Includes development and monitoring costs.

** Institute figures given for FY87 and FY88 are actual expenditures instead of obligations.

Table 1
A.I.D. Office of Population Centrally Funded Support for
Natural Family Planning and Breastfeeding

Cooperating Agency	Actual Expenditures		Obligations	
	FY85	FY86	FY87	FY88
National Academy of Sciences	\$ 15,000	-	-	-
The Pathfinder Fund	145,304	-	103,245	100,000
The Population Council	-	* 226,814	* 389,634	* 18,460
Population Reference Bureau (IMPACT)	-	23,000	10,000	10,000
Program for Applied Research on Fertility Regulation	40,000	-	-	-
Regional Training Service Agency/Asia	40,000	-	-	-
Research Triangle Institute (INPLAN)	10,000	-	-	-
RONCO Consulting Corporation	17,800	14,200	-	-
Tulane University Caribbean Operations Research Project	10,673	-	-	-
United Nations Population Fund	710,966	-	-	-
Worldwide Training Funds	25,000	-	-	-
TOTALS				
Total A.I.D./Office of Population Central Funds for NFP and BF in \$(000,000)	4.6	4.3	5.1	4.7
Institute Spending as a Percent of All A.I.D. Office of Population Central Funds For NFP and BF	0	36.5%	39.3%	69.5%
All A.I.D. Office of Population Central Assistance in \$(000,000)	128.0	133.5	115.4	114.7
Centrally Funded Support for NFP and BF as a Percent of All A.I.D. Population Assistance	2.7%	3.2%	4.4%	4.2%

Source: A.I.D. Office of Population.
 * Includes development and monitoring costs.

information was begun by A.I.D. in 1981 and continued by the Institute during its first few project years. Some CAs, however, were not responsive to the Institute's request for this information; in addition, the Institute had no way to validate the data. Concerned about the accuracy of the information, the Institute discontinued efforts to collect it.

The last four rows (on the third page of table 1) show trends in total A.I.D. Office of Population central expenditures for NFP and breastfeeding (BF) during fiscal year (FY) 1985 (just prior to the beginning of this project) through FY 1988. The first of these four rows shows that total funding for NFP and BF fluctuated during the four-year period. Since the Institute did not begin until FY86, all A.I.D. Office of Population funding for NFP and BF during FY85 was programmed through other CAs. As shown by data in the second row of totals, during its first year of operation the Institute accounted for almost 37 percent of such funding. The Institute's proportion increased slightly during its second year (to 39 percent), and then jumped to almost 70 percent of the total during FY88. The last two rows show that the percent of total A.I.D. Office of Population funds used for NFP and BF increased from 2.7 percent for FY85 to 4.2 percent for FY88.

Prior to formation of the Institute, A.I.D. had supported two international NFP organizations -- IFFLP and the Family of the Americas Foundation (FAF). A.I.D.'s cooperative agreement with FAF ended in fiscal year 1987, and there was no follow-on agreement. However, A.I.D. was in the middle of a contract with IFFLP when the Institute was started in 1985. At that point, A.I.D. requested that future support of IFFLP be funnelled through the Institute, a request consistent with A.I.D.'s desire to centralize its support of NFP.

The Institute is also expected to help A.I.D. respond to outside inquiries regarding NFP and A.I.D.'s role in supporting NFP. Disagreement and competition between factions of the NFP community required that the Institute expend considerable time and energy responding to demands and complaints directed both at the Institute and at A.I.D. during the early years of the project. The need to attend to these problems diverted energy and delayed progress during at least the first project year. Although these problems have diminished, dealing with discord from within the NFP community still consumes some of the Institute's time and attention. Although the Institute is efficient and effective in responding to A.I.D.'s needs for assistance in dealing with these concerns, it is still necessary for A.I.D. staff to devote time to the political aspects of NFP.

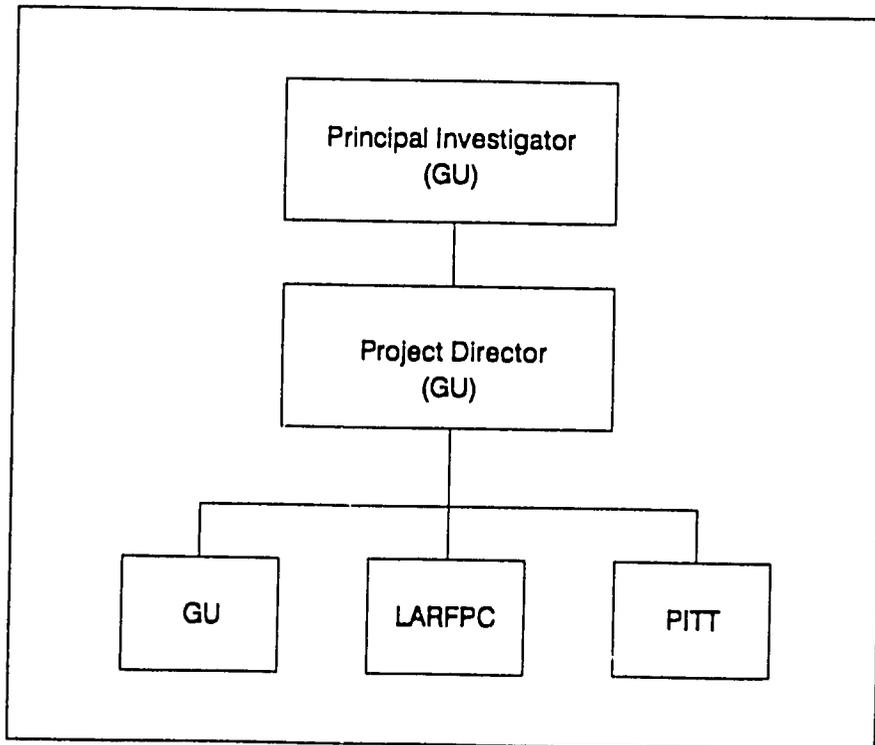
2. Project Administration

2.1 Initial Administration of the Institute

2.1.2 Relationship of the Three Program Components

At the project's inception, the three members of the Institute saw themselves as a collegial grouping of equals, particularly where matters of policy and overall direction were to be defined (see Figure 1). This view was particularly important to LARFPC and PITT. To facilitate in the administration and coordination of Institute activities, it was planned that meetings of the principal directors of the three components would be held at least twice a year. Each component was to do its own subcontracting for work related to its role in the project.

Figure 1
Original Institute Structure



GU, as the primary recipient of the award from A.I.D., included on its staff both the principal investigator and the project director, and was thus established as the lead institution. The GU component soon began to see itself essentially as the Institute and assumed control of the project's direction and management with only minimal consultation with the other members of the Institute. This assumption of primacy, together with the project director's managerial style, caused serious stresses in the relationships between GU and its two collaborators.

Despite the difficulties experienced, individual staff members at LARFPC and PITT adapted to the change in the status of their involvement and have continued to make significant contributions to Institute activities. Nevertheless, the level of trust between GU and the other two members of the consortium was badly damaged. Several staff members at all three institutions have resigned from the project.

It should, of course, be noted that the cooperative agreement is between A.I.D. and GU, with LARFPC and PITT included through subagreements with GU. As the prime recipient, GU is responsible for overall management of the agreement and is accountable to A.I.D. for its successful implementation. This, along with the geographical separation of the members of the Institute and the proximity of GU to the offices of A.I.D., has made it appropriate for GU to take the lead in many Institute decisions.

2.2 Present Administrative Structure

In April 1989, the project's principal investigator realized that the Institute was experiencing major problems, particularly with regard to staffing, and arranged for an independent management review. As a consequence of this review and with the concurrence of the A.I.D. CTOs, the Institute was restructured in July 1989. As shown in Figure 1, the original structure of the Institute was based upon the three institutional components of the project. Its new structure, outlined in Figure 2, is organized around the major focuses of the Institute's work. In essence, the Institute is now GU with LARFPC and PITT functioning as subcontractors; the concept of a consortium of equals has not existed for some time.

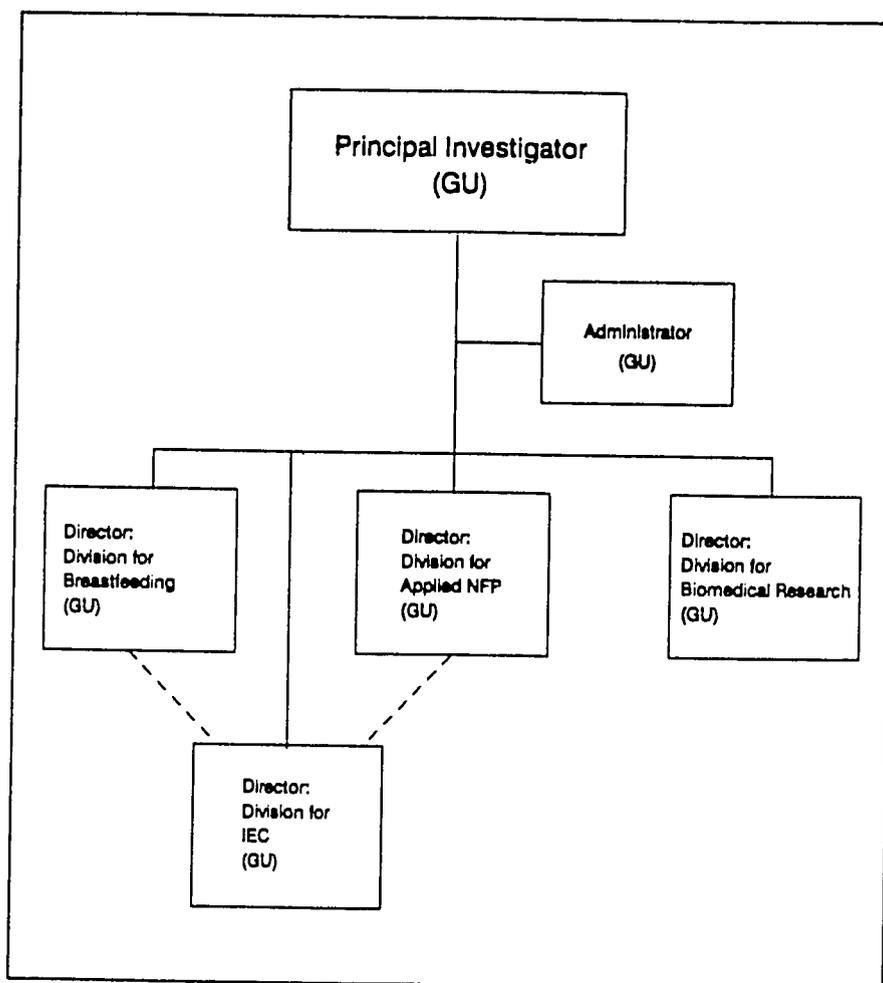
The restructured Institute functions through four divisions. The director of each division is responsible for the activities in his or her division, reports directly to the principal investigator, and has personal access to the A.I.D. CTO for the project. The Division for IEC interacts closely with the Division for Breastfeeding and the Division for Applied NFP. These three divisions in turn interact with LARFPC and with PITT. Overall coordination of the project rests with the principal investigator, who is assisted by a competent administrator.

Since the reorganization, each division director makes an annual work plan. (Previously, this was done by each of the three institutions working collaboratively, with the results combined into a single, Institute-wide work plan.) An Executive Committee consisting of the principal investigator, the administrator, and the divisional directors meets weekly. The divisional directors also meet informally once a week. Although PITT and LARFPC are represented on the Executive Committee, distance prevents their representatives from attending the weekly meetings and they do not receive the minutes of those meetings.

In the six months since the reorganization, the new administrative structure has proved to be an improvement over the previous structure: administration is more efficient; lines of communication are clearer; there is increased communication among staff; and PITT and LARFPC can deal with each other directly instead of going through someone at GU. There remain, however, considerable interpersonal stress, competition, and a lack of trust and teamwork among staff at GU and between GU and PITT. The project has already lost some very good people due to interpersonal problems, and the situation is not entirely resolved.

The success of the Institute under this new structure will depend largely on the ability of the four directors to work collaboratively. The role of the principal investigator is critical to ensuring that this occurs. Given his many other responsibilities, it remains to be seen whether he can maintain his current level of participation. Although his major career interests have been in other aspects of obstetrics and gynecology, and he had not done previous work in either NFP or family planning in LDCs, the principal investigator is intellectually interested in the issues and has become increasingly involved in the work of the Institute.

Figure 2
Present Institute Structure



2.3 The Technical Advisory Group

The cooperative agreement called for a TAG of about 12 members representing the disciplines required by the project. Its functions were to

- advise the Institute and the project's CTO,
- assist the Institute in developing projects,
- review proposals and recommend specific amendments or modifications where appropriate (based upon criteria approved by the CTO),
- monitor funded projects, and
- provide general assistance to the Institute and the CTO as requested.

It was expected that the TAG would meet three or four times each year. The TAG held its first meeting in Washington, D.C., in February 1986, and has met six times since then. The membership of the TAG and the dates and places of meetings are provided in Appendix B.

TAG meetings have been expensive both in terms of staff time and money, and the expectation that all projects should be reviewed and approved by the TAG often resulted in considerable delays (see Section 2.5 regarding the project review process). At the same time, the discipline of preparing for the TAG meetings may have been helpful in that it required the Institute to summarize and analyze all project activities at least once a year. The TAG has also provided an essential function in that it has either individually or collectively provided peer review of proposed Institute projects.

The broad nature of natural family planning issues, ranging from laboratory bench research to service delivery in small LDC villages, has made it difficult to sustain the interest of some of the more specialized members of the TAG during its meetings. The TAG has addressed this problem and considered whether it should divide into separate specialist sections. This it has chosen not to do, since most members are interested in contributing at a broader level. Although it appears that the TAG has endeavored to fulfill the role assigned it, both at its meetings and at other times on an individual member basis, the interaction between the TAG and the Institute has not functioned as efficiently as it might have. This is perhaps reflected in the decision to hold only annual TAG meetings during the last two years of the project.

All told, it was probably inappropriate to expect an advisory committee to perform some of the functions it was originally assigned. An advisory committee should advise, but not have responsibility for approval of project undertakings. The TAG was given neither the resources nor the structure to execute decision-making responsibility.

At this point, the role of the TAG seems to have evolved to suit the task at hand. The TAG has become essentially an overseeing advisory committee for the Institute. In this role it may best function in the future, with a majority of members who have a broad perspective on NFP and LAM. For advice on highly specialized areas of work, the Institute has sought and continues to seek separate consultations when appropriate using individual TAG members as consultants.

2.4 The Establishment of Project Priorities

Throughout the process of setting priorities among possible projects and approaches the Institute has been responsive to advice from A.I.D. and, by and large, has followed recommendations made by the TAG. The Institute has been slow to establish a strategy; instead each division has been encouraged to develop possibilities related to its own area of responsibility and expertise. The project budget limited the amount of funds that could be spent overall and specified what proportion of the funds should be used for certain kinds of activities. Annual work plans have been built up from specific projects, with adjustments to conform to budget constraints and to achieve the proper balance between divisions. Individual proposals have been judged on their intrinsic qualities and not in regards to overall priorities. During the first few years of the project there was more interest in getting things started and in the quality of proposed activities, and less in achieving objectives which had been determined to be priorities.

2.5 Project Review Process

The Institute's complex review process has caused considerable delay in moving project proposals forward and in completing written products.

The review process used during the first years involved the following steps: 1) The person trying to get a project started would submit a proposal to the project director (at GU); she would edit it and request revisions; it might go back and forth several times. 2) Once both parties

were satisfied with the proposal, it might await the next meeting of the TAG (possibly six or more months away). Alternatively, some proposals were mailed to TAG members for review. 3) The proposal would then go back to the originator for any revisions requested by the TAG. 4) The proposal would go back to the project director again. 5) Finally, the proposal would go to the A.I.D. CTO, a busy person who could not always get to it quickly; once she did, she usually requested some kind of revision.

Due to the administrative reorganization, the following process is now being followed: 1) Written proposals are sent to all members of the Executive Committee, who are asked to respond within 10 days. 2) The person who originated the proposal is expected to revise it within one week of receiving responses from the Executive Committee. 3) This person then asks the A.I.D. CTO for advice regarding whether or not the proposal should be sent to outside reviewers. Some projects do not require this. Those that do are sent to two or three persons not associated with the Institute who have appropriate expertise. When the external reviews have been received, further revisions are made as necessary. (At present, only the director of the Division for Breastfeeding utilizes this particular step.) 4) The proposal is then simultaneously sent to the Executive Committee (for its information) and to the A.I.D. CTO (for a final decision).

Biomedical studies also go through Georgetown University's human subjects review process.

2.6 Institute Staff

2.6.1 Staff Strengths

The Institute has well-qualified professional staff, some with established international reputations, and ready access to expertise in the computer sciences.

Many of the staff are bilingual in English and Spanish and some are multilingual. The director of the Division for IEC at GU also speaks fluent French, as do some of the staff at IFFLP. In most cases, the Institute works through local organizations, the leaders of which are at least bilingual and can build a language bridge between the English-speaking Americans and local people who speak a different language.

Appendix C provides a list of past and present Institute staff and the percentage of time dedicated by each to the project.

2.6.2 Areas of Concern

Although the reorganization has provided a better administrative structure to support the increase in emphasis on breastfeeding (see Section 1.3.2), the breastfeeding division is still undersupported in terms of staff. The director of the Division for Breastfeeding is in need of professional assistance and additional secretarial support. She is in the process of hiring a professional associate, but her need for additional secretarial support has not been addressed.

In addition, there are needs with regard to the project's computer capability. GU's system has not been coordinated -- some staff have one kind of equipment, some another, and some have none. GU is in the process of changing to a uniform system. Computers are much less available at LARFPC, even though its need is great. LARFPC produces voluminous training materials and could use a desk-top publishing capability. The Institute's need for word processing will increase as projects mature to the stage where more reports will need to be prepared.

2.7 GU's Administration of the Cooperative Agreement

GU considers it highly appropriate for the Institute to be sited in a Catholic university, finds the Institute's international activities to be in keeping with new University policies, and has shown strong support for the Institute. The directors of each division of the Institute have been accorded faculty status and the Institute is housed in first-class facilities.

The University's administration of the Institute's affairs and finances have been conducted in a straightforward and business-like manner. Any delays in administrative processes that have occurred are no more than might be expected from any large academic institution.

Although GU's overhead costs are charged at 59 cents per contract dollar, the overhead on subagreement funds is limited to 36 percent of the first \$25,000. Overall, 17 percent of project funds have been used for overhead. Over the last two years, the Institute has channeled some routine expenditures, such as travel, through LARFPC in order to take advantage of its lower overhead rate.

2.8 Institute Relationships with Related Organizations

In addition to its relationship with the IGAB, discussed in Section 1.3.2, the Institute maintains relationships with many other related organizations.

2.8.1 NFP Organizations

The Institute interacts with natural family planning organizations through its association with IFFLP, through relationships which each of its organizational units (GU, LARFPC, and PITT) have with local NFP associations, and through involvement of several staff members in the National Coalition for Natural Family Planning. This interaction includes participation in meetings, exchange of technical and annual reports, sharing materials on NFP and breastfeeding, and collaboration on projects.

2.8.2 World Health Organization

The TAG and the WHO Task Force for Natural Regulation of Fertility have met together on several occasions, most recently in August 1989, to discuss projects and activities of mutual interest. In addition, the director of the Institute's Division for Applied NFP is associated with the Task Force as a collaborating agency scientist, and the manager of the WHO Task Force is invited to all meetings of the TAG.

Institute staff have contributed to three WHO publications: *Breastfeeding and Child Spacing: What Health Workers Need to Know*; *NFP: Its Role in Family Planning*; and *Community Based Distribution: Its Role in Family Planning Services*.

The Institute's collaboration with WHO has been facilitated by a strong, ongoing relationship between A.I.D. and WHO.

2.8.3 International Planned Parenthood Federation (IPPF)

The Institute maintains a good relationship with the IPPF. Institute staff gave presentations at the IPPF Regional Conference in Brazil in 1989. In addition, they have reviewed NFP-related proposals and materials developed by IPPF and its affiliates; provided training and technical assistance to IPPF affiliates in NFP; and they have involved IPPF staff in numerous meetings.

2.8.4 Other A.I.D. CAs

The project paper calls for the project to provide "technical and material assistance to other A.I.D. CAs, Contractors, Grantees, PVOs, etc., who have specific needs in terms of NFP." There has been some confusion as to whether the Institute should assume primary responsibility for NFP activities within the A.I.D. family of CAs, or whether it should encourage and help other CAs to incorporate NFP activities into their other work. Both A.I.D. and the Institute are responsible for this lack of clarity. It is clear, however, that the long-term goals of the project cannot be achieved unless other organizations are encouraged to support and promote the use of NFP and LAM.

Other CAs see the Institute as a good source of expertise on NFP, and they call on the Institute when they think they need help. The Institute, however, could have done more to reach and work with the other CAs: it has explained to the CAs why they should work in NFP; it has not done enough to help the other CAs do it. The CAs are busy and money is short. Many are highly skeptical about NFP and want to believe that the Institute relieves them of the responsibility to work in this area. Indeed, other CAs have decreased rather than increased their work in NFP subsequent to the beginning of this project (see Section 1.5).

A.I.D. CAs are more likely to use Institute materials regarding LAM than they are to become involved in NFP. This is because they have been convinced that women can use LAM as a good family planning method for the first six months postpartum and that breastfeeding women should not use combined oral contraceptives. Its work with breastfeeding also provides the Institute with an entree to maternal and child health care workers and organizations.

The Institute has used other CAs effectively as collaborators to improve its own work. For example, the IMPACT project (at the Population Reference Bureau) helped the Institute design the poster and brochure cover for one of its primary publications, *Natural Family Planning: A Good Option* (see Section 5.2); Family Health International has conducted research with the Institute; and the International Health Program at University of California at Santa Cruz helped to organize and teach the Institute's three main courses for NFP instructors (see Section 5.4).

2.8.5 The National Institute for Child Health and Human Development

The clearinghouse and main source of financial support for biomedical and behavioral family planning research in the United States is the National Institute for Child Health and Human Development (NICHD) at the NIH, located in Bethesda, Maryland, near Washington, D.C. The director of the Institute's Division for Biomedical Research also has a part-time position in the intramural research program at NICHD. In 1987, the Institute's Division for Biomedical Research and NICHD co-sponsored a meeting of experts on non-radiometric hormone assays. The meeting was held at NIH, and its proceedings were co-edited by an Institute staff member and the director of the Center for Population Research at NICHD.

Although the director of the Institute's Division for Breastfeeding is currently involved with several review committees for NICHD, the Institute has not had adequate interaction with the individuals who manage NICHD's programs of extramural research. Two of these programs -- one related to the development and evaluation of contraceptive methods and one which focuses on demographic and behavioral research related to fertility and the use of contraception -- have particular relevance to NFP. NICHD sponsored the only large clinical trial of NFP ever conducted in the United States (at Cedars Sinai Hospital in Los Angeles); however, that research was conducted during the 1970s, and NICHD has not supported other NFP research since then. As a major funder of research on NFP in LDCs, the Institute should try to establish a collaborative working relationship with these other branches of NICHD.

2.9 A.I.D.'s Monitoring of the Project

Although the project has had three different A.I.D. CTOs during its first four and a half years, the original CTO has functioned as co-CTO with his successors. The current CTO assumed responsibility for the project in March of 1988.

Most of the interaction between the Institute and A.I.D. has been between GU and A.I.D. None of the A.I.D. CTOs has ever visited LARFPC; therefore, it is unlikely that they fully understand the resources that are available through this project.

A.I.D. has monitored and, in fact, served as mentor to this project to an unusual extent. This came about at least in part because at the project's inception the Institute lacked expertise in NFP research. In contrast, the first CTO had a long history of involvement in NFP research and more expertise in this field than any member of Institute staff. Although at times the Institute has felt that A.I.D. was overly directive and too involved in the day-to-day operations of the project, all evidence suggests that A.I.D.'s interventions have been constructive. Most importantly, A.I.D. required the Institute to give a large subcontract to IFFLP. The involvement of IFFLP has been critical to the Institute's success.

3. Project Funding

3.1 Funding Levels

The project paper was approved for \$20 million over a five-year period. The cooperative agreement between GU and A.I.D. had a ceiling of \$15 million, of which \$13.4 million will have been spent by the end of the fifth fiscal year. At the beginning of the fourth year, a decision was made to extend the project for a sixth year; an additional but as yet unspecified allocation will be made to cover the last year. Because that allocation will raise the total beyond \$15 million, the ceiling will have to be raised. If the ceiling were not raised, spending would have to drop by almost 50 percent during the sixth year. See Table 2 for information on the utilization of funds by year.

There has been one buy-in for \$260,000 from A.I.D.'s Child Survival Account to support the Institute's work in breastfeeding.

The decision to extend the project for a sixth year and to add additional funds coincided with A.I.D.'s request for the Institute to play a more active role in work related to breastfeeding. The U.S. Congress is clearly interested in A.I.D. having an adequately funded and coherent breastfeeding program; the additional support to the Institute was intended to provide for this. As noted in Section 1.3.2, A.I.D. has also asked the Institute to serve as the secretariat for the IGAB. The Institute expects A.I.D. to add \$190,000 to the continuing agreement specifically to support the IGAB secretariat. In addition, the Institute has requested \$130,000 from the A.I.D. Offices of Health, Nutrition, and Women in Development (WID) to support a study of the impact of women's employment on breastfeeding, which will be conducted for IGAB.

3.2 Expenditures by Organization

Table 2 also presents information on utilization of project funds by GU, LARFPC, and PITT, as well as amounts used by other U.S. subcontractors and amounts subcontracted to LDC organizations. Approximately \$1.7 million has been used to support activities conducted by IFFLP.

3.3 Expenditures by Project Element

Table 3 presents information on the allocation of funds for the main project elements, as suggested in the original cooperative agreement, and actual allocations, including projected expenditures for the last two years of the project. Actual expenditures will be close to what were called for in the cooperative agreement, except that less has been spent for technical assistance and more for other NFP activities, especially support of actual programs.

Table 4 shows the purposes for which GU, LARFPC, PITT, the other U.S. subcontractors, and the LDC subcontractors used their project funds. The largest single activity funded by GU was biomedical research (38 percent of GU's total funding), whereas LARFPC used 83 percent of its funds for IEC and training. PITT's funds were nearly equally divided between social science research (38 percent) and operations research (34 percent). Most expenditures by U.S. subcontractors were for biomedical research (43 percent) and "other" (48 percent). IFFLP's subcontract accounts for most of the expenditures in this latter category. Funds spent by LDC subcontractors were primarily for IEC and training (33 percent) and operations research projects (28 percent).

Table 2
Utilization of Funds, by Fiscal Year,
by Each Organizational Component of the Institute,
by other U.S. Subcontractors, and by LDC Subcontractors

	FY86	FY87	FY88	FY89	FY90	FY91*	TOTAL \$*	% of TOTAL
GU	\$ 743,191	\$ 891,874	\$1,333,335	\$ 903,407	\$1,134,343	\$ 518,306	\$ 5,524,456	\$ 36.8%
LARFPC	230,221	380,893	287,814	415,958	736,102	360,321	2,411,309	16.1%
PITT	282,448	222,326	363,200	308,718	284,943	200,000	1,661,635	11.1%
OTHER US	48,422	210,171	543,860	806,020	571,286	272,446	2,452,205	16.3%
LDC**	264,116	294,823	763,601	814,180	599,442	214,233	2,950,395	19.7%
TOTAL \$	\$1,568,398	\$ 2,000,087	\$3,291,810	\$3,248,283	\$3,326,116	\$1,565,306	\$5,000,000	\$100.0%
% of TOTAL	10.5%	13.3%	21.9%	21.7%	22.2%	10.4%		

Source: Prepared by GU project staff.

* Projection based on original ceiling; actual allocation will be somewhat higher.

** Includes contractual subagreements only. Does not include TA, materials, etc.

**Table 3
Utilization of Funds, by Project Element**

Project Element	% called for In Coop. Agmt.	Actual and Projected Use (%)					Average for Project Period
		FY86	FY87	FY88	FY89*	FY90*	
Research							
Biomedical Research	20 %	15 %	24 %	22.3 %	25.0 %	26 %	22.5 %
Operations Research	15 %	-	15 %	13.2 %	12.1 %	16 %	11.3 %
Social Science	10 %	-	9 %	11.5 %	10.6 %	7 %	7.5 %
Total Research	45 %	15 %	48 %	47.0 %	47.7 %	49 %	41.3 %
IEC and Training							
IEC and Training	25 %	67 %	23 %	24.8 %	13.7 %	15 %	28.7 %
Technical Assistance	20 %	12 %	16 %	16.8 %	12.1 %	7 %	12.8 %
Other NFP Activities	10 %	6 %	13 %	11.4 %	26.5 %	29 %	17.2 %
	100 %	100 %	100 %	100.0 %	100.0 %	100 %	100.0 %

Source: Prepared by GU project staff.

* Estimate

Table 4
Utilization of Funds, by Project Element and Type of Organization

	GU	LARFPC	PITT	Other U.S.	LDC	% of Total
Research						
Biomedical	35.5%	-	-	42.5%	8.8%	22.5%
OR	11.7%	-	33.6%	2.7%	28.1%	11.3%
Social Sci.	6.0%	-	37.7%	5.4%	11.3%	7.5%
Subtotal	55.2%	-	71.3%	50.6%	48.2%	41.3%
IEC/Training	18.4%	82.6%	-	1.0%	32.7%	28.7%
TA	12.5%	16.2%	26.7%	-	-	12.8%
Other	13.9%	1.2%	2.0%	48.4%	19.1%	17.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Prepared by GU project staff.

Table 5 shows actual expenditures (in U.S. dollars) for breastfeeding, including a subcategory of work specifically focused on LAM as a method of contraception, and for NFP and fertility awareness, with one subcategory of expenditures for NFP-only services and another subcategory for other aspects of NFP and fertility awareness. Given current plans, a little less than one-third of the project funds will be used for work related to breastfeeding, with that amount almost equally divided between LAM and other breastfeeding work. A little more than two-thirds of the funds will be used for NFP and fertility awareness; only a small proportion of these funds have been used for work to incorporate NFP into multimethod family planning services. Because the increased emphasis on breastfeeding did not start until 1988, the funding figures for the last half of the project would show a greater proportion of funds going to breastfeeding.

3.4 Expenditures by Geographic Region

Table 6 shows the allocation of Institute funds by geographic region. Although the largest proportion of effort has been targeted to Latin America, expenditures for Africa have increased and are now almost on a par with those for Latin America. About one-third of the funds go for multi-regional or worldwide program efforts. More went to Latin America in part

Table 5
Utilization of Funds for Breastfeeding
and for Natural Family Planning and Fertility Awareness

	<u>Breastfeeding*</u>			<u>Natural Family Planning & Fertility Awareness**</u>			Total
	LAM	Other	All	NFP Only	Multi-method	All	
General Admin	\$ 149,500	\$ 143,645	\$ 293,145	\$ 246,443	\$ 821,156	\$ 328,599	\$ 621,744
Biomedical Research	556,019	312,761	868,780	1,387,968	438,306	1,826,274	2,695,054
Behavioral Science	286,650	154,350	441,000	654,945	274,055	929,000	1,370,000
Operations Research	266,380	290,745	559,125	789,165	249,210	1,038,375	1,597,500
IEC, Training	301,654	760,451	1,062,105	1,460,404	237,504	1,697,908	2,760,013
TA	256,557	171,038	427,595	539,992	254,113	794,105	1,221,700
Other	274,182	106,626	380,808	1,525,018	214,774	1,739,792	2,120,600
Subtotal	\$ 2,092,942	\$ 1,939,616	\$ 4,032,558	\$ 6,603,935	\$ 1,753,118	\$ 8,354,053	\$12,386,611
Overhead	439,518	419,519	859,037	1,386,826	367,526	1,754,352	2,613,389
Total \$	\$2,532,460	\$ 2,359,135	\$ 4,891,595	\$ 7,990,761	\$ 2,117,644	\$10,108,405	\$15,000,000
% of Total	16.9%	15.7%	32.6%	53.3%	14.1%	67.4%	100.0%

Source: Prepared by GU project staff.

*LAM - Breastfeeding activities and projects specifically related to child spacing.

BF/Other - Activities and projects related to other aspects of BF, such as nutrition, general BF promotion, etc.

**NFP Only - NFP activities and projects that focus only on family planning methods which require periodic abstinence.

Multimethod - NFP activities and projects that support NFP services in multimethod FP programs, compare NFP to other methods, etc.

because the original project director had wide knowledge of, and experience with, family planning in that region. In addition, the predominance of Roman Catholicism in Latin American culture made it a good first place for the project to work. IFFLP's interest and extensive work in Africa explains the level of effort in that region.

Table 6
Utilization of Funds, by Geographic Region

	FY87	FY88	FY89	FY90	Project Average
Latin America	41%	29%	34%	35%	35%
Asia/Near East	11%	15%	9%	7%	10%
Africa	4%	28%	25%	30%	22%
Multiregional/Worldwide	44%	28%	32%	28%	33%
All	100%	100%	100%	100%	100%

Source: Prepared by GU project staff.

3.5 Adequacy of Funding

It does not appear that the Institute has been hampered by inadequate funds. There is additional work that could be done, or done sooner, if there were more money. However, the Institute has made significant progress and there is a natural and necessary sequence to much of the work. Also, the Institute was a new organization which needed to do much groundwork, and the absorptive capacity of the field, so far, is limited. More money would not necessarily have produced much more effect, at least in the area of NFP.

The situation is different with breastfeeding, which is a much larger, more well-developed field. Many international organizations are interested in breastfeeding, and its target group -- breastfeeding women -- is huge relative to the proportions of couples who choose to use NFP, which is probably less than 10 percent in all countries except Sri Lanka (where it is 15 percent), Mauritius (17 percent), Peru (11-18 percent) and Poland (30 percent). The Institute's Division for Breastfeeding has developed a cogent strategy and work plan and could use additional funding productively. It is important, however, that the large, ready-made absorptive capacity of the breastfeeding field not be allowed to overwhelm the Institute, which must still work to create a greater absorptive capacity for NFP.

There is also some shortage of funds for things such as printing more copies of materials, travel to monitor projects, and personal computers. Some of these shortages arise from

failures of planning or prioritization. In such a large and complex project, involving units located in different institutions, some of these problems are inevitable. The two main shortages appear to be 1) professional assistance and additional secretarial support for the director of the Division for Breastfeeding (as noted in Section 2.6.2), and 2) money to support printing and distribution of many more copies of some of the Institute's most important documents.

4. Research

4. Research

Forty-six percent of project funds have been used to support research. A.I.D.'s project paper cited "gaps in our knowledge of NFP" and specified three types of research -- biomedical research, operations research, and social science research -- needed to fill those gaps.

4.1 The Establishment of Research Priorities

The project paper suggested a very wide scope of research objectives and a wide variety of possible studies -- much more than could possibly be accomplished within the budget, staff levels, and time frame of the project; it was not expected that all of these ideas could be pursued. The cooperative agreement contained a more focused but still large set of possible research objectives. Thus, there was always a need to select from among many possibilities. Except in the area of biomedical research, however, where the possibilities and priorities were clearer and easier to define, the early phase of the project was governed more by a felt need to get something going, to find opportunities, and to begin to work; less attention was given to narrowing the field of attention in order to focus on specific goals. It should be remembered that, with the exception of LARFPC's training of a few LDC physicians and nurses, none of the three principal organizational components of the Institute had prior experience with NFP in LDCs. A start-up and learning phase was unavoidable. Even so, the project could have moved ahead faster if it had developed clear priority objectives at an earlier point.

As the project has played out, decisions to pursue specific research projects have been influenced by various factors, including advice from A.I.D. and from the TAG; the desire to take advantage of opportunities which developed as a result of other work done by the Institute or to follow-up and continue work begun by others; the quality of some of the proposals received from outside institutions; prior working relationships between specific staff members and specific LDC institutions; and the pre-existing professional interests and skills of senior researchers at GU and PITT.

Throughout this process, two critical areas of research have been largely overlooked: 1) field ("clinical") trials to measure effectiveness and continuation rates associated with various NFP methods and with possible improvements in those methods, and 2) studies of the human behavior involved in contracepting through periodic abstinence.

The only field trial of an NFP method that has been undertaken by the Institute is classified as "operations research" (see Section 4.5.2) and is not rigorous enough to assess adequately the effectiveness of the altered method which is being tested. Clinical trials were included in the section on biomedical research in the project paper, but were not specified in that section of the cooperative agreement. Instead, the biomedical research section of the cooperative agreement calls for "high quality clinical research on the physiology and endocrinology of the fertile period, and the development of new methods for predicting ovulation," especially "a simple and reliable home test." The project's Division for Biomedical Research is headed by an endocrinologist and has focused on studies which require endocrinologic methods and expertise. The endocrinologic work being pursued by the Institute is extremely important and has great potential. The need for this basic research was perhaps under emphasized in the project paper; its emphasis in the cooperative agreement has been positive. In addition, the development of an easy-to-use home test kit (see Section 4.4) for reliable prediction and detection of ovulation might make NFP an attractive option for millions of women in Western countries, and increased use of the method in those countries might make the method more attractive to couples in LDCs.

Although both the project paper and the cooperative agreement included behavioral studies under social science research, only one actual behavioral research project has been started. Almost all of the social science research undertaken to date has been secondary analysis of demographic data (which is valuable and will make a major contribution to the field). The institution responsible for the social science work (PITT) does not have adequate staff and experience to conduct the behavioral studies that are needed. PITT has always had a demographer but did not have a behavioral scientist until 1989, thus, its heavy focus on secondary analysis of demographic and other data.

Because of the importance of field trials and behavioral studies, they are treated as separate categories of research in the remainder of this report.

4.2 Constraints on Research

A number of problems make it extremely difficult to conduct research on NFP in LDCs: Most NFP workers are volunteers who can only give a few hours per week to this work. NFP is a "movement" which derives its energy from committed persons; members of the movement want objective data but are strongly biased in favor of NFP. They are motivated to give their time and effort for a variety of reasons, including religious commitment and the social and emotional satisfaction of working for a good cause within a close-knit community of like-minded colleagues and friends. Some local project coordinators have low levels of literacy. In most cases, the organizational structure is either a church or a small and informal local organization. Most of these organizations do not have experience in the conduct of research, or the internal structure needed to implement and monitor a rigorous research protocol. Indeed, efforts to impose the controlled conditions required for high quality research could have a negative impact on the social environment of an NFP organization. In the long run, anything which diminishes the social rewards for NFP volunteers could compromise the movement.

Prejudice, even hostility, against NFP on the part of many persons working in mainstream family planning service delivery organizations increases the difficulty of conducting research on NFP in those settings. The difficulty of recruiting and retaining large numbers of NFP users for a prospective study and of expecting women or couples to accept assignment to NFP or another family planning method according to a research protocol are discussed through an example presented in Section 4.5.2. Although some questions can be answered with good data from relatively small numbers of NFP users, large numbers of subjects are needed in order to get reliable pregnancy rates. It is also hard to find large numbers of LDC women who want to space pregnancies but are not breastfeeding. It might be possible to overcome some of these problems by conducting certain kinds of NFP studies through LARFPC in Los Angeles, where there are large communities of relatively recent immigrants from virtually every country in the world.

In addition, all research findings on NFP should be interpreted in the context of the fact that, in most places, NFP is being used by a small and self-selected subset of the population. Individuals who choose to use this method may differ from the larger, more heterogeneous population in ways that are difficult to measure but which are of inherent importance for successful use of NFP; e.g., studies have found use of NFP to be associated with higher than average levels of marital satisfaction and self-esteem.³ Findings based on self-selected users cannot be extrapolated to the larger population simply by adjusting for demographic and other easily measured characteristics.

³Madigan, S.J. "Response to Open-ended Questions." *Report on the 1984 Philippine Periodic Abstinence Survey, vol. 1.* Xavier University, Philippines. Research Institute for Mindanao Culture, 1985.

4.3 The Need to Distinguish between Program Evaluation, Operations Research, and More Rigorous Kinds of Research

There has been a lack of clarity between projects on the following continuum: 1) evaluation of projects for which the primary purpose is expanded or improved service delivery or training, 2) operations research to develop and test local alterations in service delivery, and 3) field trials to measure the effectiveness of changes in the method itself. Although all of these require the same elements, i.e., training, management of a service delivery system, and the collection, processing, and analysis of data, they have different emphases and purposes. Many types of expertise may be needed to support any one project, but each project should be led by a person with the expertise necessary to support the central purpose of the project. This has not always been the case.

4.4 Biomedical Research

A large number of potential areas of biomedical research were identified in the cooperative agreement. In addition, the Institute subsequently sought project proposals from interested investigators through advertisements in relevant medical journals. At the first TAG meeting in February 1986, a program of biomedical-related research was agreed upon for implementation by the Institute.

Several of the projects undertaken, including some carried out in-house, have not really constituted original research. It should, of course, be kept in mind that the Institute began the project with little previous experience in NFP-related biomedical research and that the Department of Obstetrics and Gynecology at GU lacked laboratory resources for even performing hormone assays. Thus, a learning phase was required and it was necessary to establish and standardize assay methods, a task not best done solely in pursuing innovative research. The Institute now has a laboratory resource at GU with the ability to provide appropriate and cost-effective support for its projects.⁴

A list of the Institute's current or recently completed biomedical research projects is provided in Appendix D. Three of the most important studies have been selected for review and comment.

The first two of these studies have aimed to develop a reliable method for ascertaining the fertile days in a woman's menstrual cycle through simple test kits utilizing dipstick-type indicators that would measure urinary estrogens and pregnanediol. The hope is that this work will lead to the development of an inexpensive and accurate kit with which a woman could detect her fertile days through a simple procedure performed at home.

Estrone glucuronide is one of the major urinary estrogen metabolites. The rising levels of this excretory metabolite during the days immediately preceding ovulation correlate well with the increasing serum concentrations of estradiol and follicular growth that precede ovulation. Peak levels of estrone glucuronide are observed approximately one to two days before ovulation. It has been hypothesized, but not yet proved, that the beginning of the fertile period may coincide with the commencement of the preovulatory rise in urinary levels of estrone glucuronide. In addition, ovulation is followed by a marked increase in ovarian secretion of the hormone progesterone. Many NFP users recognize the end of the fertile period by the progesterone-

⁴It should be noted that the Department of Obstetrics and Gynecology has itself contributed significantly to the cost of these facilities.

induced shift in basal body temperature; another signal could be the rise in urinary levels of the progesterone metabolite, pregnanediol glucuronide.

4.4.1 The Development and Application of An Enzyme Assay for Estrone Glucuronide. Principal Investigator, Dr. W. Lasley, University of California, Davis.

This project involves the development and production of a prototype enzyme immunoassay (of the ELISA type) for urinary estrone glucuronide in a home test kit format for fertility detection. ELISA-type assays for estrone glucuronide have been developed by a number of investigators in recent years, so this was not an innovative project. (Dr. J. B. Brown in Melbourne, Australia, for example, already has an enzyme immunoassay test-kit for estrone glucuronide and pregnanediol glucuronide under field trial for NFP applications.) Although it appears that the project has resulted in the development of an assay system providing easy visual assessment of results, technically the system, even if further simplified, would be relatively cumbersome in contrast to a dipstick-based method of measurement.

4.4.2 The Development of Novel Estrogen Tests to Predict the Fertile Period in Women. Principal Investigators, Dr. F. Kohen and Dr. G. Barnard, Weizmann Institute, Israel.

This project is directed towards developing a novel immunoassay system for measuring steroids, other hormones and drugs using anti-idiotypic and anti-paratypic monoclonal antibodies. This innovative research, if successful, would provide the technical feasibility for dipstick-type fertility tests based upon measurement of urinary estrogens and pregnanediol. The assay system would also offer the sensitivity to measure salivary concentrations of estradiol and progesterone.

This project has already been productive in developing time-resolved fluoro-immunoassays for urinary estrone glucuronide and for pregnanediol glucuronide. The Institute's principal investigator and the director of the Division for Biomedical Research traveled to Israel in January 1990 to assess reported significant developments in the major aspect of the project. They found that a breakthrough had indeed occurred in the successful development of novel antibodies which could be used to develop an assay system. A TAG team member who accompanied them confirmed that a significant and novel advance in immunoassay methodology appears to have been achieved by the Weizmann group.

The developments at the Weizmann Institute are encouraging and exciting; nevertheless, a major technological step requiring considerably more research will be needed to convert this new laboratory assay procedure into a simple, do-it-yourself at-home test kit.

4.4.3 A Study of the Outcome of Pregnancies in Natural Family Planning: Fetal Effects. Principal Investigator, Dr. J. L. Simpson, University of Tennessee.

This is a longer-term prospective cohort study to investigate whether pregnancies associated with NFP show increased rates of spontaneous abortions and of liveborn infants with external anomalies or low birth weight. Two centers in Chile, and one each in Colombia, Peru, Italy, and the United States, are contributing data to the study. Conceptual cycle NFP charts and the outcome of pregnancy are being evaluated on the basis of NFP method failures, user failures, and pregnancy planners. The data returned from Chile and from Italy are apparently of a high standard. There is some concern, however, with regard to the uniformity of teaching of NFP

methods among the centers which might give rise to misinterpretation of data. The design of the data collection form is intended to obviate such errors.

This is the most costly of the biomedical research projects (proposed budget \$443,933) and perhaps the most controversial. Strong arguments could be given against this project's having been undertaken in the first place. Workers in the NFP field and probably the large majority of investigators in reproductive medicine do not believe, on existing evidence, that, due to an increased incidence of conceptions involving "aging gametes," NFP use may be associated with an increased risk of birth defects. Nevertheless, the Institute decided, with support from the TAG, to proceed with the study. In any case, due to the high quality and the international reputations of the investigators, the project should put to rest a lingering question about NFP. The study will also contribute important findings related to the duration of fertile sperm survival in the female reproductive tract and associations between the timing of conception and the sex of the fetus.

The largest portion of the project's budget (\$161,176) goes to Johns Hopkins University for data analysis. Approximately \$100,000 has been saved from the project budget because of the decision to limit the use of NFP centers in the U.S. for the data collection.

4.4.4 Biomedical Research in Support of LAM

The Institute is also conducting basic research related to lactational amenorrhea as a contraceptive method. This work includes a study to elucidate the endocrine mechanisms that control lactational amenorrhea; studies of relationships between breastfeeding practices, the return of fertility, and the signs and symptoms used for NFP; evaluation of the effectiveness of various types of breast pumps to prolong amenorrhea; a study of the effects of maternal and child nutrition on lactational infertility, and efforts to identify hormones (or other body chemicals) that herald the return to fertility and that are present in early morning urine or in breastmilk itself.

The long-term purpose of most of these studies is to determine whether women with lactational amenorrhea can use NFP methods (i.e., measurement of basal body temperature and observation of cervical mucus), or possibly some simple test of accessible body fluids, to predict and/or detect their first post-partum ovulation. If this were feasible, women could rely on the natural fertility suppression associated with lactation for as long as it lasts and could accurately determine when to begin to use another contraceptive method.

Findings from the studies conducted to date suggest that there is a relationship between the breastfeeding pattern established during the first three months of lactation and the total length of amenorrhea; that NFP signs may not be very helpful to lactating women who are trying to predict their first ovulation; and that, because several menstrual cycles during breastfeeding are not typical, a woman who relies on NFP may be especially vulnerable to unplanned conception during the months immediately following her first post-partum period.

4.4.5 Future Biomedical Research

Biomedical research during the remaining period of the cooperative agreement is expected to be principally concerned with completing the outcome of pregnancy study and with the Weizmann project. Irrespective of the Weizmann project, numerous NFP questions still remain to be resolved by research. Two such questions center on 1) fertility during the perimenopausal years and the effectiveness of NFP methods at this time, and 2) the duration of the fertile period as defined by mucus symptoms among women in LDCs, especially whether it is significantly shorter than among women in developed countries (as suggested by findings from the *WHO Multicenter Study of the Ovulation Method*).

Although many of the breastfeeding studies have not yet been completed, it already appears that this will be an important body of work. In this area, discouraging findings may be as important as encouraging ones. Efforts to teach family planning workers that lactational amenorrhea can be a reliable method of contraception are difficult because this information contradicts what they have previously been taught. It is particularly important that the new teaching be based on accurate and complete evidence.

4.5 Field ("Clinical") Trials

4.5.1 Importance of Field Trials

The project paper called for clinical trials to assess the effectiveness of various currently available NFP methods and to determine whether the effectiveness and acceptability of current methods can be improved by modifying their rules to reduce the required length of abstinence; this kind of study was categorized under biomedical research. The project paper also cited the need to quantify the effectiveness advantage of "modern NFP methods" (Billings ovulation method, temperature method, and sympto-thermal method) as compared to calendar rhythm. Although women with regular menstrual periods have been the subjects for almost all trials of modern NFP methods, there has never been a prospective clinical trial on the use of calendar rhythm by women with regular periods. Such studies could be very important: Calendar rhythm is widely known, is used by many couples in all areas of the world, and is relatively easy to learn; if it were found to be reasonably effective, family planning programs could help women who are trying to use rhythm to use it more effectively. The project paper also suggested clinical trials of the effectiveness of modern NFP methods as used by lactating women, pre-menopausal women, women with long and irregular menstrual cycles, and women who are poorly nourished or have frequent genital tract infections.

The biomedical research section of the cooperative agreement also spoke of the need to determine whether NFP can meet the needs of women with these conditions and to determine whether NFP methods can be improved by modifying their rules to reduce the required length of abstinence. However, the cooperative agreement did not mention clinical trials as a part of biomedical research; instead (as discussed in Section 4.1) it called for research on the physiology and endocrinology of the fertile period and the development of an ovulation predictor which is not sensitive to fluctuations in a woman's health, nutrition, or reproductive status (i.e., lactating or pre-menopausal) as a means to reduce the period of abstinence required for effective NFP.

Only one clinical trial has been undertaken by the Institute; it was classified as operations research and has been managed by a person whose main expertise is in NFP training and materials development. The current staff of the Institute does not have the expertise necessary to conduct clinical trials; however, these skills are potentially available through the Research Unit at LARFPC (which conducted clinical trials of the cervical cap) or through collaboration with the department of epidemiology at either GU or PITT, or with FHI or various universities.

4.5.2 A Controlled Study of the Simplified Muco-Calendar Rhythm Method

NFP is complicated to learn and use and requires many consecutive days of abstinence. Most failures (unintended pregnancies) that occur with NFP result from user error or "risk taking"; failure rates are low, between 0.5 percent to 3 percent, when the rules of the method are followed. Wider and more effective use is limited by the difficulty of teaching, learning, and using the method, and by the unwillingness of many people to conform to rules requiring extended periods of sexual abstinence. Thus, there is considerable interest in finding simpler ways to practice the method and in altering the rules to reduce the number of abstinent days. Even though such changes might increase the failure rates associated with perfect use, actual failure rates could decline if the changes resulted in fewer errors and less risk taking.

The Institute has supported and assisted in the conduct of a potentially important controlled trial of a simplified NFP method which requires fewer days of abstinence and builds on and supports the user's experience with calendar rhythm. The study will measure pregnancies among the experimental and control groups, classified as "method failures" (pregnancies which occur during correct use of the methods), "user failures" (pregnancies which occur because of errors in use of the methods), and "risk taking" (pregnancies which occur when users knowingly break the method rules). In addition to testing a variation of the NFP rules, the project will evaluate use of a written guide which the instructors use while teaching the users, and which the users are supposed to keep in their homes as a guide. The study will also gather data on user satisfaction with the methods, reasons for stopping use of the methods, and continuation during a 12-month period.

This project is of special interest because the altered NFP rules build on the potential user's prior experience with calendar rhythm. If couples using the new method have fewer unplanned pregnancies than couples taught to use the usual NFP rules, the findings will be important. The study is being conducted at the Research Institute for Mindanao Culture, at Xavier University in the Philippines. The Jesuit priest who heads the Research Institute is a highly competent demographer and statistician, and the Research Institute is well respected. This should be an ideal setting for a careful study.

Unfortunately, the Institute has classified this study as an "operations research" project to develop and test an alternative approach to teaching NFP. However, what is being tested here is not only a variation in the training but actually a change in the method itself. With NFP, the rules are the method. When we want to try a different dose pill, we submit it to a clinical trial. Therefore, a study to test the effectiveness of a change in NFP rules should be conceptualized and conducted as a field trial. In this case, a potentially important controlled trial of a variation of the rules has been managed by an Institute staff member who, although highly competent, is an expert in training but not in research. She has provided skilled and consistent oversight of the training. Significant problems with the user's guide were identified and have been solved; it appears that the quality and consistency of the training have been protected and assured. However, there has not been consistent and appropriate research oversight. An Institute staff member from PITT contributed to the original research design, but because of personnel turnover, a different PITT staff member accompanied the project manager (from LARFPC) during the first mid-project monitoring visit. An epidemiologist who is not assigned to the Institute project but is on the LARFPC staff has begun to provide research support and will accompany the project manager on an upcoming monitoring trip.

It appears that the project is experiencing significant problems: One-third of the subjects are breastfeeding (which was not allowed in the original research design). At least 45 percent of the experimental group dropped out before completing 12 months of use, and more may do so before the study ends. The number remaining in the experimental group is low, and the project manager has received no information on the number of subjects in the control group. The study findings will be suspect because of the high proportion of dropouts, and the numbers will be too small for a reliable determination of the incidence of pregnancy.

In addition to problems related to the lack of consistent research oversight, this study illustrates the difficulty of conducting adequate clinical trials of NFP in LDCs, in particular the difficulty of enrolling and keeping adequately large numbers of couples in a long-term prospective study. The Xavier team had to interview 2,300 couples to find 520 who were willing to participate. Most people who want to contracept already hold strong opinions either for or against NFP; few will tolerate being randomly assigned to use NFP or another family planning method. Thus, it may be virtually impossible to conduct large randomized clinical trials. It should be noted that these problems have occurred in a study being conducted by an unusually sophisticated research institution in a country in which there are many users of NFP.

4.6 Operations Research

Operations research (OR) has been part of the project since its inception. It is a hybrid category of research. An issue of *Population Reports* devoted to operations research in family planning programs⁵ noted that it is not easily defined and means different things to different people, including "research techniques to diagnose and correct operational problems, pilot projects to demonstrate new approaches, evaluation of ongoing programs, experimental efforts to test different activities." The emphasis is on developing practical solutions in situations where it is not possible to employ rigorous experimental designs. "It generally means small-scale projects that can produce results quickly, using whatever research methods are appropriate" and with "less concern for the exact replicability of results and more attention to solving local problems identified by people working in individual programs." The director of the Research Division at A.I.D.'s Office of Population defines OR by its function, as "any research conducted for the purpose of improving service delivery."

4.6.1 Responsibility for OR Projects

Persons with a variety of academic and experiential backgrounds might be qualified to conduct operations research. It does not flow from a specific discipline, like endocrinology, biochemistry, epidemiology or anthropology, each of which implies expertise in a particular set of subject matter and research skills.

Responsibility for the operations research arm of the project has shifted over time. At first it was to be at PITT; the director of the Institute's component there is an expert in program evaluation. The director of the Division for Breastfeeding at GU also has OR expertise. When she joined the GU staff, she assumed oversight of operations research. Now that she is responsible for the entire Division for Breastfeeding, however, it is unrealistic to expect her to provide technical oversight for all of the OR projects as well. Because every OR study is part of a training, IEC, or service delivery project, and each project has a specified manager, responsibility for OR has become diffused among staff with a wide variety of experience, skills, and education. Some OR projects are managed by staff at PITT, some by staff at GU, and some are managed from LARFPC.

Now that the Institute is in its fifth year, no new studies are being started and most ongoing studies are past the stage of needing input on research design. However, it will soon be time to begin to analyze, interpret, and present the data from these studies. As things have evolved, it is likely that each component of the Institute will pretty much take care of the OR studies that are being managed by its own staff. LARFPC has begun to use non-Institute staff from its Research Unit to back-up OR projects being managed by its trainers. The current situation of diffused authority for operations research may work out very well; there is research expertise at all three components of the Institute, as well as at IFFLP. In addition, the insights of the actual project managers, most of whom have extensive experience in training, IEC, and/or NFP service delivery, will be especially important in understanding the study results.

4.6.2 OR in Progress

Only a few of the Institute's OR studies have been completed. Results from one OR study conducted in Mexico has corroborated other findings which suggest that hospital childbirth care is associated with diminished breastfeeding. Studies now under way will

⁵Series J, Number 31, May-June 1986.

- compare the results of three different community-based interventions to promote breastfeeding in northern Mexico;
- compare two different ways to support breastfeeding women, and observe the effect of these interventions on the length of LAM;
- assess the quality, acceptability, and cost-effectiveness of group teaching as an alternative to individual NFP instruction in Mauritius;
- conduct a controlled test of the effect of using the breastfeeding guidelines on the length of exclusive breastfeeding and the length of LAM among women served through a program in Latin America; and
- explore the feasibility of integrating NFP into a multimethod family planning program in the Philippines; this study will also compare the use-effectiveness of NFP with pills, condoms, and injectables provided through clinics with and without support from community-based workers and determine why women prefer to use one or another of those methods.

4.6.3 PITT's Computerized NFP Data Base

Most NFP programs teach users to record observations regarding their cervical mucus and/or basal body temperature on monthly charts. A biostatistician at PITT has computerized data from more than 16,000 monthly charts produced by more than 2,500 American NFP users, and has designed software to facilitate analysis of these data.⁶ Most of the women in the data set (2,166) were using the CC-BBT method; a smaller number (136) were using another sympto-thermal method; and 204 were using the ovulation method. The data set contains information from an average of six months of charts per woman. The program stores 1) basic demographic data on each woman, 2) basal body temperature data related to the menstrual cycle, 3) mucus observations as made by the woman during each cycle, 4) menstrual cycle length and dates, 5) information on menstrual pain, breast sensitivity, protected and unprotected coitus, lactation, use of oral contraception, pregnancy, miscarriage, other disturbed basal conditions (e.g., medications, illness), and 6) whether or not the woman was trying to conceive. The computer program can produce a replica of each chart, make simple interpretative statements about each chart, identify charts that contain obvious errors, and provide a concise description of the interpretation of previous charts submitted by an individual woman.

This data base was started with charts from NFP users in Pittsburgh. The biostatistician who developed this data base was a key member of the staff of the original PITT component of the Institute. Some of the findings (which have yet to be published) are as follows:

- Although proponents of different NFP methods often believe that the method they teach is better than any other way of observing, recording, and interpreting the signs and symptoms associated with the fertile period, these data show that two different techniques for interpreting temperature charts (temperature averaging vs. coverline) are equally effective.
- Cervical mucus charts from women using the sympto-thermal method are as accurate as the cervical mucus charts of women using the ovulation method.

⁶Rockette H., N. Obuchovski, H. Klaus, and W. Stevenson. "Assessment of chart quality in a natural family planning delivery system." University of Pittsburgh Graduate School of Public Health, unpublished.

- The quality of charting is not associated with the incidence of unplanned pregnancy -- i.e., sloppy charters are not more likely than tidy charters to experience unplanned pregnancies.
- The great amount of variability in month-to-month cycle length for most women means that it may not be possible to simplify the rules without increasing the number of method failures. Five percent of women have so much variability that they really cannot use NFP. However, it may also be possible to identify a subset of women who have extremely invariable cycles, and who, therefore, could use NFP with particular ease and reliability. This is an area in which further work is needed.
- The accuracy of methods which rely in part on basal body temperature readings is not affected by whether the temperature is taken orally or vaginally. Further analysis is being conducted to determine how much difference it makes if the woman uses a centigrade thermometer instead of a fahrenheit thermometer.

Although a great deal of important work has already been completed, some work has not been finished, and there are many other potential uses for this data set and for computerized analysis of similar data from charts of LDC women who are using NFP:

- The data are being used to describe the frequency of minor illnesses which affect basal body temperature, to determine what women should do when their charts are disturbed by temperature changes related to illness, and to observe the effect of having some temperature measurements which are missing.
- The computer program makes it possible to profile a local NFP program rapidly and at a reasonable cost; this capacity could be very useful for further operations research. For instance, the system has developed baselines for such parameters as the percentage of biphasic charts and the percentage of charts with a well-defined mucus peak. Data from a new NFP program could be examined to determine how its charts compare to these norms. This data system also offers a fairly simple way to evaluate variations in NFP teaching.
- The data could be used to calculate the probability of pregnancy associated with intercourse on specific days of the cycle, and to define, for each set of NFP rules, the number of days of abstinence required to reduce the unintended pregnancy rate by a specified amount. (This very important work is not part of the current budget and plan.)

This computer program has also been used to correlate information from NFP charts with endocrine information (i.e., measurements of hormones directly related to ovulation) from the same women. PITT is supporting the Institute's Division of Biomedical Research in this work.

4.7 Social Science Research

The project paper and cooperative agreement called for a very broad agenda of social science research. The project paper called for the development of information regarding the psychological, sociological, and cultural factors that significantly affect both the demand for NFP and its overall effectiveness. This was to include research regarding factors that affect the demand for and choice of NFP, profiles of successful and unsuccessful users, cultural barriers to NFP, effects of NFP on the relationship between husband and wife, and possible benefits of fertility awareness education for women who choose to use a different method of family planning. The cooperative agreement reworded this agenda but did not change it except to suggest that

information on the determinants of public support for NFP programs in LDCs is also needed, though it is of lower priority than the other social science objectives.

4.7.1 Secondary Analysis of Existing Data

For many years, A.I.D. has supported several organizations to conduct surveys to measure fertility, contraception, and basic indicators of maternal and child health in specific LDCs. Most of the social science research conducted to date by the Institute's unit at PITT has been secondary analysis of these data in order to measure and examine the use of NFP, breastfeeding, and LAM. This work was not called for in either the project paper or the cooperative agreement and is being pursued instead of some other kinds of social science research. It appears to be a cost-effective, productive, and important line of research.

The small number of NFP and LAM users limits what can be accomplished with the data from many of the surveys. In all but a few countries, NFP users constitute only a small subset of the survey subjects, in some cases too few for meaningful analysis of factors associated with the use of NFP. In addition, except for three countries (Peru, Sri Lanka, and the Dominican Republic) in which special NFP modules were used, surveys conducted before 1987 only asked about "rhythm," not about other types of NFP, and did not collect enough information on breastfeeding to allow for calculation of the use of LAM. The Institute has arranged for more specific questions to be asked during a new round of Demographic and Health Surveys (DHS) which will be conducted in 29 mainly Asian and African countries. The problem of small numbers will probably persist, however, except in a few countries (e.g., Peru and Sri Lanka) where NFP is particularly popular. The 1986 survey in Peru collected data on more than 500 NFP users and asked about two NFP methods; it found that 96 percent of NFP users were using calendar rhythm. Good data are also expected from a survey which the U.S. Centers for Disease Control will conduct in Mauritius (a high NFP-use country) in the spring of 1990.

The 1986 survey in Peru asked women about their use of various kinds of contraception over time. There is a great need for more of this kind of information. Clinical trials of contraceptive methods drop subjects as soon as they become pregnant or at the end of a specified period of time, usually one year. It would be important to know 1) what happens to women who become pregnant while using NFP, i.e., what, if any, method do they use when the pregnancy is over, and 2) what becomes of the women who are still using NFP successfully at the end of a year, i.e., what proportion of couples who use it for one year will continue to use it throughout their entire reproductive lives? These kinds of longitudinal data are needed for all methods, but especially for NFP, because most of the costs associated with providing the method occur at the beginning of the period of contraception. It is impossible to understand the relative cost of teaching couples to use the method unless something is known about how long each couple might be expected to use it once they learn it.

The Institute for Resource Development, Inc. (IRD) conducts the DHS surveys. Staff from PITT, GU, and A.I.D. collaborate in generating hypotheses to be tested with these data. IRD provides clean data tapes, and, in some cases, tabular data. A demographer at PITT is responsible for most of the analysis and the preparation of reports. In the past, he was assigned to this project on a part-time basis and was not always able to produce work according to agreed-upon schedules and deadlines. This has resulted in dissatisfaction among Institute staff at GU, stress among Institute staff at PITT, and strained relationships. It is not clear whether PITT has been too slow or the original expectations were too high; probably some of both. In addition, some of the problems may have been due to delays in the availability of the data tapes. Nevertheless, it is clear that planning and communications at PITT have not been adequate. If the deadlines were unrealistic, this should have been recognized and communicated to colleagues at GU at a much earlier stage. Some changes have been made; the demographer will now be working on these analyses nearly full time. Much of the work is coming to fruition. The quality

of the analyses is good; the reports being produced at PITT are well written and should result in influential publications. The demographer at PITT plans to write some of these as a co-author with collaborators from each country studied, who can enrich the papers with information on the specific sociocultural milieu. The demographic studies will also be used to generate questions for further research. In the end, this work will be very productive for NFP.

In addition to the survey data, the Institute is using data from service delivery projects to identify characteristics associated with choice, continuation, and effectiveness of NFP.

4.7.2 Secondary Analysis of Data on Breastfeeding and LAM

The Institute has conducted a thorough analysis of breastfeeding, food supplementation, and postpartum amenorrhea, contraception and abstinence in Peru, based on DHS data collected in 1986. Although the Institute originally planned to conduct a similar analysis on data from seven other countries, because of delays on the part of IRD due to data tape inaccuracies which, in turn, led to delays in product finalization, the new contract includes a revised plan that will instead concentrate on cross-national comparisons of data from all 29 countries in the current round of DHS surveys. The Institute also plans to produce a one-page summary of information targeted to policymakers in each of those countries.

The goals of this analysis are to understand how breastfeeding and other infant feeding practices affect fertility and how contraception affects breastfeeding and fertility. In at least two countries (Senegal and Sri Lanka), it is apparent that very early supplementation of breastfeeding shortens the period of amenorrhea despite prolonged breastfeeding. Other findings indicate that the decline in breastfeeding (associated with urbanization and increases in women's education and employment) has slowed in several countries.

There are also plans to use the data to examine the nutritional effect of exclusive breastfeeding for longer than six months, and to study the relationship of breastfeeding and birth spacing on infant and child mortality. Demographers at IRD will do some of these analyses.

A large amount of data relevant to the use of LAM has been collected during various studies. Almost all of the analysis to date has been limited to the first six months of breastfeeding. The Institute wants to begin to examine the utilization of LAM beyond the end of the sixth month. Since secondary data analysis will depend on collaboration with those who developed the data bases, it will most likely be done with those institutions.

4.7.3 Behavioral Research

The effectiveness of NFP is excellent if the rules are followed. The reasons it is not well and widely used are sexual, psychological, social, and cultural -- areas subject only to behavioral research. However, so far the Institute has started only one actual behavioral research project, a prospective study of psychosocial factors that influence the choice, continuation and successful use of NFP among clients of a program in Mauritius.

Review of Behavioral Research on NFP. PITT has conducted an extensive review of published and unpublished behavioral research on NFP from throughout the world. Since many of the studies are not published, the review took a long time to complete. The review notes that most of the studies have been methodologically and/or conceptually deficient, that few reports summarize their findings with respect to other currently available information, and that there are

few consistent "conceptual threads guiding research efforts."⁷ Variables may not be mutually exclusive and/or clearly defined, sampling is not systematic, and little attention is paid to limitations related to use of convenience samples. Many studies consist only of satisfied users of the methods, unmarried couples are frequently excluded, and samples are small.

The review is thorough, well written, and a valuable piece of work in itself. This paper will be disseminated through the Institute's mailing list, and the authors hope to publish it in *Studies in Family Planning*. Although it may be too late to begin additional behavioral research studies during the remainder of the current project, the review could give direction to a focused behavioral research program during a follow-on project. It points out, for instance, that there is a need for studies that focus on NFP teachers (providers) as well as users, and for studies of the knowledge, attitudes, and practices of the husbands of women who use NFP. In addition, many findings from this review will be useful to NFP teachers and program managers. For example, several studies have found that a high percentage of couples who use NFP have non-coital sexual activity during the fertile period; some couples view the fertile phase as an opportunity to explore non-coital ways to provide and obtain sexual pleasure, while others perceive abstinence as having a negative effect on their marriage. Many studies show that a large proportion of couples (almost half of respondents in a 1984 Philippine NFP Survey) regularly use another contraceptive method during the fertile period. Medical safety and the absence of side effects were the main reasons why couples in the Philippines choose to use NFP; only 2 percent cited "moral acceptability" of the method as a reason. Other studies have found that individuals who continue to use NFP for a long time are more likely than those who discontinue its use to have tried and been dissatisfied with other methods, and that NFP users are more likely to be spacing (rather than limiting) their pregnancies, and are more willing to have additional children.

There is a clear and widely acknowledged need for much more research into the behavioral aspects of the use of NFP. Why has so little been accomplished? One reason is because this kind of research is difficult to do well. PITT's review of the literature concludes that, "while psychosocial research on NFP is still in its infancy, the situation is not much better with respect to psychosocial studies of other contraceptive methods." At the same time, some good research has been done by others, and the Institute could have made more progress in this area. Institute staff at PITT, however, did not include anyone with actual behavioral research experience; its staff had many other important and relevant skills, but no actual experience in psychosexual research. Thus, with a plate full of other opportunities, especially the large amount of DHS survey data available for closer analysis of the use of NFP and LAM, behavioral research was put into a "let's study how to study it" mode.

Expert Meeting on Psychosocial Issues in NFP. In early 1988 (halfway into the expected five-year term of the cooperative agreement), the Institute held an Expert Meeting on Psychosocial Issues in NFP. The major outcomes of the meeting were 1) the determination that a clear conceptual framework is needed to guide behavioral research related to NFP, 2) the identification of components of such a framework, 3) a discussion of issues related to the design and implementation of such research, and 4) the development of a set of sample questions on personal and couple factors which could be used to augment existing data collection instruments. Those participating in the meeting encouraged the Institute to collect psychosocial data even in countries unable to implement complex studies, recommended prospective studies to collect data on both women and men, and emphasized the importance of studies which address sociocultural influences and the male role in sexual relationships. As of January 1990, the report from this meeting had not yet completed the Institute's internal approval process; thus distribution of the

⁷Sharma, P.K. and M.F. Sevick. *Psychosocial Aspects of Natural Family Planning: A Review of Selected Literature*. University of Pittsburgh Graduate School of Public Health, December 1989.

report, and of the list of sample questions, is still in the future. However, PITT has collected a set of questionnaires which have been used to gather psychosocial data on NFP users in various LDCs and provides copies of these to other researchers upon request.

5. Efforts to Support, Expand, and Strengthen NFP and LAM in LDCs

5.1 Overview

More than half of the Institute's resources have been used for activities which are directly related to improving NFP services in LDCs -- 32.7 percent for IEC and training and 19.1 percent for other NFP activities (see Table 4 in Section 3.3 for a breakdown of project budget allocations).

For its first few years, the Institute focused almost exclusively on efforts to support NFP-only organizations. This was because GU was new in this field and needed to develop credibility within the NFP community. More recently, the Institute has also started to reach out to the multimethod family planning community.

During the project start-up phase, the Institute informed people about its mission and identified organizations to work with through a variety of ways:

- It sent information about the Institute and a general solicitation of interest to A.I.D. CAs, the international population/family planning community, and the NFP organizations which belong to IFFLP.
- Various Institute staff members had some pre-existing contacts within the LDC NFP community; the Institute started its work with the people and institutions already known.
- The Institute learned which other organizations had bid on the project and invited them to participate in the work of the Institute.

The Institute's work in LDCs is intended to achieve several objectives: to influence policymakers; to train NFP trainers and instructors; to inform people about NFP and LAM through IEC outreach activities; to improve the management of NFP service delivery programs; and to increase the number of people working in NFP.

5.2 Activities Designed to Influence Policymakers

■ A 15-page booklet, *Natural Family Planning: A Good Option*, was published in July of 1989. It explains the history and evolution of NFP, discusses reasons why people use NFP, summarizes information on effectiveness and continuation, and explains how NFP services are provided through NFP-only programs and how they can be incorporated into national multimethod family planning programs. This document is effective because it presents NFP in a factual and objective way. The data on effectiveness include the very good results from Mauritius, which has a well-developed program, as well as data from the WHO NFP study, which included a wider range of societies and found lower effectiveness and continuation rates.

■ The Institute is in the final stage of developing a similar 28-page booklet on breastfeeding. It will include information on the benefits of breastfeeding and what can be done to promote and support breastfeeding.

- The Institute plans to produce one-page summaries of breastfeeding data from 29 LDCs; each one will clearly present the policy implications of these findings.
- The Institute has summarized demographic data on NFP, breastfeeding, and LAM in very readable and interesting reports, which will make this information available to policymakers. The reports have, however, been slow in getting out. Oral presentations have been made, but the papers have not yet been published.
- The Institute has developed a formula to use survey data to calculate the prevalence of LAM. As a result, it will be possible to include LAM as a method of contraception when calculating overall contraceptive prevalence rates. The CAs that conduct the family planning and fertility surveys have revised their data collection tools to be able to gather the more specific information which is needed to detect LAM.
- The director of the Division for Breastfeeding participated in the influential Bellagio Breastfeeding Consensus Meeting which was held in 1988.
- An Institute-supported subproject held four one-day NFP motivational seminars for 300 policymakers in India. This project was proposed by an alumnus of the Institute's English-language course for NFP instructors.
- With support from the Institute, the IGAB has become an effective force within the international health policy arena. In July-August 1990 the IGAB will convene a meeting to stimulate renewed commitment to the promotion, support, and protection of breastfeeding among high-level, international and national policymakers. The Institute is the only component of the IGAB with special expertise and interest in the contraceptive benefits of breastfeeding. Other members of the group focus primarily on the benefits of breastfeeding for infant health. It is hoped that the upcoming meeting will result in the development of a comprehensive United Nations/WHO strategy to make the 1990s a "decade of progress in breastfeeding" throughout the world.
- The Institute sponsored a panel discussion on breastfeeding policy at the National Council on International Health meeting in June of 1989. The panel included UNICEF, FHI, A.I.D., and World Bank representatives. As a result, a discussion of LAM may be included in the next edition of *Where There Is No Doctor*.

5.3 Efforts to Promote NFP, LAM, and Fertility Awareness among Multimethod Family Planning Programs and Child Survival Programs

Early efforts to incorporate NFP into multimethod family planning projects have not been very successful, either in the U.S. or in LDCs. Several factors may contribute to this lack of success: 1) Some of the motivation for people involved in community-based distribution of family planning services is related to the profits that can be realized from selling commodities; with NFP, there are no commodities to sell. 2) Workers in multimethod clinics feel that NFP takes too long to teach. 3) Many family planning workers have been taught that NFP is ineffective. 4) There has not been enough high-level support for NFP among influential family planning leaders.

5.3.1 NFP and Fertility Awareness

- The Institute is working with several groups (ranging from CAs to WHO) in NFP and fertility awareness activities (via materials, involvement in technical meetings, etc.) and has included trainers from multimethod family planning programs in training activities.

■ So far, the Institute has been involved in four projects aimed at incorporating NFP into multimethod family planning programs.

- A project with the Family Planning Organization of the Philippines (see Section 4.6.2.) is studying how to integrate NFP into its multimethod service delivery program. Thus far, the project has found the administrative system to be unsupportive of clinic personnel trained to provide NFP services, leading to the conclusion that it is better to use a person who is already committed to NFP to provide that service at a clinic, and to train multimethod family planning workers to counsel and refer women to an NFP specialist.
- The Institute has played a supportive role in two projects (funded by other organizations) to add NFP to multimethod family planning projects in Brazil and Kenya. In Kenya, the Institute has also funded a project to train NFP instructors who will provide services in Ministry of Health (MOH) hospitals and clinics.
- The Institute has provided technical assistance to a family planning organization in Guatemala (APROFAM) to enable it to analyze NFP-user charts as a method for assessing the quality of NFP instruction. The project is being funded by the IPPF.
- The Institute is planning to convene a meeting to develop a strategy for integrating NFP programs into multimethod family planning service delivery programs. The meeting, which is being planned for 1991, will include representatives from family planning organizations in Brazil, Nepal, and other countries.

5.3.2 LAM

■ The Institute is working with the faculty of nursing departments in several Latin American universities and nursing staff from PAHO on a three-phase project aimed at developing a breastfeeding curriculum for Latin American schools of nursing. Twenty people from 10 countries are working on this project, two from each country (a nurse educator and an MOH staff member). These 20 people spent a week at GU developing a consensus outline for the curriculum, which focuses on the importance of breastfeeding and how to support it. The Institute's Division for IEC is developing a manual based on the outline. Once the manual is pilot-tested and evaluated, the curriculum will be integrated into the nursing curriculum in each of the 10 countries.

■ Institute staff have published original articles on their NFP-related research in international professional journals which are read by family planning program administrators, and the midwives, nurses, and physicians who provide family planning services. In addition, they have contributed to major review journals.⁸

■ The Institute has prepared the document "Guidelines for Breastfeeding in Family Planning and Child Survival Programs." Although it has not been printed yet, the Institute plans to disseminate it through CAs and USAID missions. The first print run will be 1,000 copies in English; it is already obvious, however, that this will not be enough: a premature announcement about the document in *Mothers and Children* (a newsletter for people working in international maternal and child health) has already resulted in 300 requests.

⁸For example: Labbok, M. and J. Queenan: "The use of periodic abstinence for family planning," and Albertson, B. and M. Zinamon: "The prediction of ovulation and monitoring of the fertile period," in the 1989 volumes of *Clinical Obstetrics and Gynecology and Advances in Contraception*, respectively.

- The Institute has produced a one-page (both sides) fact sheet, "Breastfeeding for Child Spacing." This document does not actually contain facts on the subject, but rather provides information on the Institute and its capabilities in regard to this subject and invites inquiries.

- An Institute project in Chile is producing data on the efficacy of the LAM method and a handbook on how to incorporate breastfeeding support into clinic settings. This prospective intervention study is designed to assess the impact of a comprehensive hospital and free clinic follow-up breastfeeding support intervention on mothers and babies during the six-month period following birth.

- Institute staff take advantage of opportunities to speak about LAM to groups of health professionals and policymakers, and have provided technical assistance to some A.I.D. CAs, e.g., the Centre for Development and Population Activities (CEDPA) and the Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPEIGO).

- FEMAP (Federacion Mexican de Asociaciones Privadas de Planificacion Familiar), a federation of private, non-profit neighborhood health programs in Mexico, began a project in 1986 that focuses on the use of mass media and home- and community-based health education to improve mothers' knowledge about breastfeeding and to increase the numbers of women who breastfeed exclusively during the first four to six months postpartum.

5.4 Training NFP Instructors

There has been a lack of quality training for NFP instructors. The Institute has focused both on training more people and on increasing the skills of people already working in the field. A difference in philosophy and approach to training between staff at LARFPC and at GU, however, has been a source of disagreement. With experience, however, the two groups have developed a more mutual view of what is needed. For the future, the Institute would like to develop national training teams and regional consultants. There also remains a great need for better evaluation and operations research to learn, for example, which training methods work best and how much training is needed.

Major accomplishments in this area to date include the following:

- Three Training of Trainers (TOT) regional courses -- These three-week courses were conducted primarily by LARFPC and the International Health Program at the University of California at Santa Cruz. The courses included

- One in English held in Santa Cruz, California in 1987, which had 20 participants from 12 countries;
- One in French, held in 1989 in Nairobi, Kenya, which included trainees from Haiti, Africa, Mauritius, and Madagascar; and
- One in Spanish in Bogota, Colombia in 1988, which was targeted at Latin American countries.

Participants were individuals who were already functioning either as NFP instructors or as multimethod family planning trainers (i.e., they already had expertise in NFP and/or in training). Many of the NFP instructors were volunteers from community-based programs who had no previous formal instruction in training methodology or the design and evaluation of training programs.

The courses were preceded by a participant needs assessment and used a participatory approach. Many of the materials which the participants took home with them had been developed during the course. Each participant was expected to design an educational plan to improve NFP training in his or her home situation.

Informal surveys of TOT participants indicate that many have begun to train clients and additional NFP instructors. As a result of second and third generation training projects, approximately 1,200 additional NFP instructors have been trained.

The Institute is publishing a newsletter for people who participated in its TOTs in English, Spanish, and French. Copies are sent to all TOT participants, NFP program administrators, the directors of organizations with which the TOT participants are affiliated, and selected USAID missions. The Institute plans to ask alumni of the courses to complete an evaluative questionnaire.

Institute staff have visited many of the TOT alumni to provide technical assistance for specific follow-on projects.

- Guide for Natural Family Planning Trainers -- This guide, the result of several years' effort spearheaded by LARFPC, will be published within the next few months. It has been revised several times and has benefitted from the incorporation of input from Institute staff, consultants, and NFP instructors who participated in the Institute's NFP instructor TOTs.

The guide focuses on teaching methodology and how to design a program for training NFP instructors. It uses the same terms and vocabulary as the WHO manual for NFP users, which it complements. It also complements pre- and post-tests which were developed by IFFLP as a way to evaluate NFP instruction.

The guide not only provides the information to be taught, but suggests how to teach it; e.g., it offers specific questions which can be used to stimulate discussion. Because it was produced in a loose-leaf style, the Guide will be easy to revise. The Institute plans to develop short (one-day or less) workshops on how to use the manual. The workshops could be conducted immediately before or after other meetings.

The guide will be available in English, Spanish, and French, and will be distributed to all TOT participants, NFP organizations which are involved in training, IFFLP members, and others as requested. A mail-back evaluation form will be distributed along with the guide.

5.5 Innovative IEC Outreach Activities

The Institute wants to go beyond the church and health care delivery systems to inform people (especially younger women) about NFP; for example, it realizes that women's groups and educational institutions need to become involved. To this end, the Institute has supported a variety of activities.

- PROVIFA Project, Cote d'Ivoire. This project, which has the potential to reach large numbers of young women, was developed through a cooperative effort of the Institute and IFFLP, of which PROVIFA (a private local institution) is a member. PROVIFA conducts the project in cooperation with the Cote d'Ivoire Government's Ministry for the Promotion of Women which sponsors a continuing education program targeted at providing home economics courses for young women not enrolled in a secondary school. So far, 376 home economics teachers have been given a course in fertility awareness and have been helped to develop a curriculum for teaching the subject to the young women enrolled in the Ministry's continuing education program. PROVIFA

is also working to institutionalize the teaching of fertility awareness as part of the regular school program.

- ATLF Project, Lima, Peru. The aim of this 26-month project was to promote the use of NFP in areas around Lima, Peru. The project (which has been completed) doubled the number of NFP users (to 772). Project activities included an outreach campaign with television, radio, and community events; a number of IEC materials were also developed and tested as a part of the project.

The ATLF (Asociacion de Trabajo Laico Familiar) and the Institute are now gathering information to determine which outreach activities were the most successful. They hope to report this information through an article in a peer-reviewed journal.

- Demonstration Project in Cusco, Peru. This project is using radio to promote optimal breastfeeding techniques. Qualitative research methods (focus group and in-depth interviews) will be used to determine whether a series of educational radio programs and breastfeeding education and services will increase people's knowledge about breastfeeding and lead to the acceptance of breastfeeding practices that are most conducive to child survival and child spacing. Nurses and doctors in the community are being trained to support the radio messages.

- Outreach Strategies for Natural Family Planning Programs: Applying Sound Communication Principles. This is a publication that was developed as a resource for NFP programs in LDCs.

5.6 Improving the Management of NFP Service Delivery Programs

The cooperative agreement called for management training as a component of institutional support. During follow-up visits to alumni of its three main TOT courses, Institute staff have found the greatest needs to be in the areas of data management, supervision, and assessment of cost-effectiveness.

NFP organizations vary greatly in size and sophistication, from organizations which serve as few as 10 clients to organizations which serve many thousands; most have a couple of hundred clients. With this diversity, there cannot be a single approach for improving management.

It does not appear that any one component of the Institute has primary responsibility for management training. GU has subcontracted a private consulting firm to do some of this training, and IFFLP and PITT have each done some. The evaluation team was not able to assess any of these efforts very fully but learned more about the work done through PITT than about the Institute's other management training efforts. These activities include the following:

- The Institute provided some faculty and paid the expenses for some participants to attend a data workshop for NFP programs in Asia.

- The Institute subcontracted with the Development Group (a private U.S. consulting firm) to assist NFP organizations in Africa to enhance their management skills. The Development Group conducted needs assessments in several countries, and used what it learned through that process to organize two workshops (one in Zambia and one in Kenya) to address specific needs.

- The Institute (especially the component at PITT) has been working with the Kenya Catholic Secretariat (KCS) to develop, install, and train people to run a computerized management information system for the large NFP program (500 NFP instructors and 16,000 clients) run by the KCS. The purpose is to give the KCS the capacity to monitor and evaluate its own program, and

to use the information for planning. Inputs into this effort have included four weeks of training in Pittsburgh and an additional three and a half weeks of training in Kenya for two KCS staff members, and provision of two microcomputers, a power generator, and structural work to enhance the security of the buildings which house the computer. Unfortunately, one of the two people who were trained to run the system has left his job at KCS. (The possibility of turnover was the reason for training two people in the first place.) However, if the other trained person were also to leave, the entire effort would collapse. This is not unlikely, since workers with computer training and experience can command higher salaries than KCS is probably able to pay. In addition, even if KCS retains its computer competence, it is not clear that the data it collects will be valid (since many of the variables are not well defined), or that the key managers of the program will use the data as a basis for making decisions about the project. Although these concerns have arisen in connection with the management information system, they may also be pertinent to others systems that must be run by people with expertise in computer systems.

- The IFFLP Technical Assistance Project, initiated in March 1988, supports service delivery and provides technical assistance in institutional development to NFP programs in seven African countries. In addition, this project supports Action Familiale/Mauritius to provide supervisory training to NFP supervisors from several African countries.

- Institute staff at PITT are developing a data management guide for NFP programs. Six hundred copies of a preliminary edition of the guide have been produced in English, French, and Spanish; the demand for copies has exceeded supply. Although the guide was enthusiastically received when presented to the TAG, it has several problematic aspects. It was never pilot-tested and IFFLP did not have a chance to review it in draft form. It emphasizes the use of graphics to display information; however, most NFP programs will not have access to computers that can easily produce such graphics and it is not clear that pie charts and bar graphs are a particularly effective way to communicate information to people in all cultures. In addition, it is written on a higher level than is appropriate for the target audience and the reading level has not been evaluated. It is currently being revised for a second edition based on comments from users, including IFFLP staff.

- The Institute would like to develop a brief management manual based on the materials developed for the management courses it supported in Africa. This might be a cost-effective way to help the many small NFP service providers, most of which cannot be reached with other forms of management training.

5.7 Increasing the Number of People Working in NFP and LAM

There is a need for persons who can serve as consultants to assist with the development of NFP service delivery programs in LDCs, especially as regards management, and to help design and monitor NFP research. Such consultants should be based in a strong NFP organization and they should be used to assist less well-developed NFP organizations within their own regions.

Two-thirds of the Institute's projects and other activities are being conducted with or through another agency; 30 percent have been conducted by or in association with an LDC organization (see Table 7). Implementation of these activities should enhance the expertise of persons employed by or otherwise involved in these LDC-based agencies, especially as regards expertise in research, management and training methodology. At present, there are relatively few persons (in Peru, Ecuador, Cote d'Ivoire, and Mauritius) with enough expertise to be used as consultants for other programs, but the number is increasing. IFFLP has been particularly active in efforts to develop consultants based in LDCs.

Table 7
Institute Projects and Activities by Implementing Agency

Type of Project	Number and Percent of Projects by Implementing Agency					Total
	Institute	Institute + Other Non-LDC Agency	Institute + LDC Agency	Other Non- LDC Agency	LDC Agency	
Biomedical Research	8 (32%)	5 (20%)		12 (48%)		25 (100%)
Social Science Research	7 (47%)	1 (7%)		4 (27%)	3 (20%)	15 (100%)
Operations Research	1 (11%)		1 (11%)		7 (78%)	9 (100%)
Education, Communication, Training	17 (33%)	9 (17%)	2 (4%)	7 (13%)	17 (33%)	52 (100%)
All Projects as of March 31, 1989	33 (33%)	15 (15%)	3 (3%)	23 (23%)	27 (27%)	101 (100%)

Source: Data are derived from report on status of Institute projects and activities, March 31, 1989.

The Institute has also begun to use short-term consultants to augment its staff at GU. The consultants have been well selected and seem to be making an important contribution. The use of such consultants also serves to increase the number of U.S. professionals who have professional involvement and commitment in NFP and LAM.

In addition, several masters degree students and doctoral candidates at the Graduate School of Public Health at the University of Pittsburgh have worked on studies being conducted by the Institute and have consequently developed serious professional interest in NFP or LAM. GU, however, has not made an adequate effort to involve its own graduate students in Institutework, except for medical students, who work in the biomedical laboratory. Students in a variety of schools and departments, e.g., anthropology, community medicine, epidemiology, midwifery, nursing, and sociology, might become interested in this field by working on Institute studies.

5.8 Maintaining a Resource Center

The Institute maintains a resource center at GU that is available to individuals and groups working in the area of NFP and LAM. Materials are available in English, French, and Spanish. Although the Resource Center was formed to address the needs of those working with or in LDCs, materials are also available on a limited basis to anyone who requests them.

6. Other Project Activities

6. Other Project Activities

6.1 Efforts to Build a Consensus within the NFP Community

6.1.1 Disputed Issues

There continue to be differences of opinion and belief among NFP providers (see Section 1.4) with regard to the following issues:

- The teaching of fertility awareness techniques to couples who plan to use barrier methods during the fertile period. Some NFP groups believe that the use of other contraceptives is morally wrong.
- The context within which NFP should be taught. Some NFP proponents feel that NFP services should not be provided within a multimethod family planning program.
- Belief in the superiority of a particular NFP method. Some groups believe that one method is best and are willing to teach only that one. Others teach women to observe and chart all fertility signs and encourage them to use whatever works best for them.
- Qualifications for NFP instructors. Some NFP groups feel that all NFP instructors should use NFP themselves; some require instructors to be married; and some require instructors to agree in writing to neither use, teach, nor advocate the use of any other family planning method.

6.1.2 Accomplishments

The Institute has added its weight to the moderate side of each of these issues. In addition, it has provided and guided processes through which people with different opinions could work constructively together to define some common ground. These efforts have resulted in increased consensus and unity. Major accomplishments in this area include the following:

- The publication of the *Glossary of Natural Family Planning Terms*. A major purpose of the Glossary was to develop consensus regarding terms used by people working in NFP. People from five very different NFP organizations were involved in achieving this consensus.
- Institute staff are active in the efforts of the National Coalition for Natural Family Planning, a U.S.-based organization which includes some groups and individuals who are either directly involved in or help to sponsor international work in NFP.
- The Institute plans to convene a meeting in the fall of 1990 provide a forum for NFP experts to focus on NFP in LDCs. This invitational meeting will include representatives of various NFP organizations, biomedical research programs, WHO, UNFPA, and appropriate A.I.D. CAs. Advances that have taken place in the field during the last 10 to 15 years will be presented and an opportunity will be provided for small groups to begin working together to chart a course for the future.

6.2 Establishment of a Dialogue between NFP and Other Family Planning Groups

The Institute's work thus far has succeeded in bringing NFP and other family planning people together to work on common projects. Working together, these two groups can

learn to understand and respect one another's points of view and can identify common values and concerns. Some people from the family planning community, for example, believe that being for NFP means being against family planning. GU's identity as a Catholic university has helped to make it possible for the NFP people to participate in this working together, and its identity as an academic medical school has made it possible for mainstream family planning people to participate. It has been important that the synthesis of research findings has come from an institute based in a respected obstetrics and gynecology department of a U.S. medical school; its staff are seen as scientists, not promoters, so there is a heightened awareness that there is a scientific basis for NFP.

6.3 Dissemination of Research Findings and Other Institute Products

The Institute has at least a four-fold strategy for disseminating information about NFP and LAM: 1) to educate the scientific and professional community by presenting high-quality research reports at professional meetings and by publishing research reports in peer-reviewed professional journals and brief articles in the newsletters of various organizations; 2) to use brief, well-designed pamphlets and posters to communicate messages to policymakers and others who require brief messages; 3) to disseminate "how to do it" reports and other documents utilizing a computerized mailing list which is coded to allow selection of persons and/or organizations with particular interests and/or characteristics, and 4) to give Institute TOT alumni a sense of continuing recognition and participation in the project and in the NFP network by publishing newsletters. In addition, the Institute's inclusion in several policy-making bodies provides opportunities for dissemination of information during meetings and for providing input into a variety of documents.

The Institute's major documents -- the *Glossary of NFP Terms*, *NFP: A Good Option*, *Breastfeeding Guidelines for Family Planning and Child Survival Programs*, and *Guide for NFP Trainers* -- were carefully and slowly crafted. Each was sent out for wide review and underwent many revisions. These documents should pave the way for better communication and wider cooperation than has been possible in the past; each is an important contribution which will be widely used for many years. See Appendix E for a complete list of Institute publications.

The Institute's computerized mailing list, however, is basically a "convenience" sample -- i.e., it contains the names of people who have worked on Institute projects, who have attended its meetings, who are part of A.I.D. or of the A.I.D. family of CAs, who were known to IFFLP, or who were on some other pre-existing lists. Although the list is continually revised and updated, and is probably quite inclusive of the international "NFP family," an adequate effort has not been made to ascertain who the Institute's audience should be and how to reach people who are outside of the NFP community but need information on NFP and LAM, e.g., a list of LDC schools of nursing and midwifery.

7. The Potential Contribution of NFP, LAM, and Fertility Awareness Education to A.I.D. Population Assistance Goals

7.1 NFP, LAM, and Fertility Awareness Education in the Context of A.I.D. Population Assistance Goals

Within the context of A.I.D.'s population assistance goals, continued work in NFP, LAM, and fertility awareness education is important for the following reasons:

1. NFP and LAM are safe and are the only contraceptive methods that are culturally acceptable to some people. In most cases, this is because people understand that these methods are safe; many LDC women report fear or not liking to use the other methods.
2. NFP and LAM are highly effective methods of contraception when used correctly. Studies have consistently shown NFP method failure rates of between 0.5 and 3 percent, but use-effectiveness rates hover around a mean of about 20 pregnancies per 100 woman-years. The difference is due to failure to abstain during the fertile phase of the woman's menstrual cycle. If these methods were more widely available, and if people were better able to comply with the rules of the method, NFP could make a significant contribution towards A.I.D.'s goal of reducing the incidence of unintended pregnancies in LDCs. The necessity for long periods of abstinence is a major obstacle to greater and better use of these methods. With more research, it may be possible to reduce the period of required abstinence, either by altering the method rules or by devising more accurate ways to identify the fertile period.
3. Although the more effective modern NFP methods (sympto-thermal and ovulation method) are practiced by relatively small numbers of women throughout the world, calendar rhythm is widely known. With more and better research, it may be possible to identify subgroups of women who can use calendar rhythm very effectively, and to find more effective ways to teach the method (even by radio) to women who lack access to other means of contraception.
4. Fertility awareness, (the information and skills by which a woman can determine when she is and is not fertile, or when she is more or less likely to be fertile) is a component of NFP. In addition to its use by women who are practicing NFP, fertility awareness could help other women use barrier methods more effectively. Almost all of the costs for providing fertility awareness education are "front loaded." Once a woman learns how to identify her own fertile period, she may be able to use that knowledge in various healthful ways throughout her lifetime. In addition to its integral role in NFP and its supportive role in the use of barrier methods, fertility awareness can assist subfecund women who are trying to conceive and can help women to recognize when they have conceived. This knowledge would help women to seek pregnancy-related services at the earliest possible time.
5. The hormonal suppression of ovulation associated with full breastfeeding can effectively prevent pregnancy during at least the first six months of a baby's life and reduce the probability of pregnancy thereafter. Breastfeeding is natural, culturally acceptable, and, in many countries, essential for adequate child nutrition. Here the challenge is not to introduce a new practice but to support and retain a healthy practice, especially to prevent dilution and loss of the practice as societies undergo modernization and other social change.

7.2 Profile of Women Who Use NFP and LAM

7.2.1 **How Many Women Use NFP and LAM? What NFP Methods Do They Use?**

DHS data that have been analyzed by IRD and PITT describe patterns of NFP use in 12 LDCs -- 4 in Africa, 2 in Asia, and 6 in Central and South America.⁹ Except for such surveys, NFP users are hard to count; it is hard to estimate the number of "users" because they do not consume supplies and much replication of NFP training can go on without any way to count the number of people who have been trained.

The knowledge of periodic abstinence as a way to contracept varies from a low of 16 percent in Liberia to a high of 75 percent in Brazil. In general, knowledge of this method was lowest among the sub-Saharan countries and highest among the Latin American countries. Women in all of these countries were more likely to know about another modern method of family planning than they were to know about NFP. The only two countries in which more than 20 percent of women had ever used periodic abstinence were Peru (26 percent) and Sri Lanka (39 percent). Eleven percent of currently married women of reproductive age (MWRA) were using NFP in Peru and 15 percent in Sri Lanka; another survey found that 17 percent of MWRA were using NFP in Mauritius in 1985. (NFP has been available through a private voluntary organization in Mauritius since 1963.) However, NFP is being used by less than 10 percent of MWRA in all other surveyed countries, except for Japan (12 percent in 1986) and Poland (30 percent in 1977). Nevertheless, NFP accounts for a large percent of contraceptors in some low-prevalence countries. For instance, although less than 5 percent of MWRA in Burundi were using NFP, women using NFP accounted for more than half of that country's contraceptive prevalence. Data from several countries suggest that, as the overall use of contraception in a country increases, the use of NFP also rises, but does not keep pace with increases in the use of other methods.¹⁰ It appears that there is a definite, but in most cases small, subset of women (couples) within the population of most countries who are prone to use NFP, and that they will do so even when most others around them are not using anything. An overall increase in the social acceptability and use of contraception does not encourage large numbers of additional people to start to use NFP: use of NFP is stable at about 4 percent of MWRA in the United States and several European countries (e.g., Belgium, the Federal Republic of Germany, Portugal, and Spain).

The vast majority of LDC women who have ever used NFP (more than 85 percent in every country studied) rely on calendar rhythm.

The United Nations has estimated that approximately 31 million women were using rhythm as a method of contraception as of 1987 -- 17 million women in the Western industrialized countries, and 14 million in LDCs.¹¹ This is 80 percent of the number of couples using condoms and half of the number using pills.

⁹Burundi, Ghana, Liberia, Morocco, Sri Lanka, Thailand, Brazil, Colombia, the Dominican Republic, Ecuador, Peru, and Trinidad and Tobago.

¹⁰Spieler, J. and S. Thomas. "Demographic aspects of natural family planning." *International Journal of Gynecology and Obstetrics*. Suppl. 1:133-144, 1989.

¹¹United Nations: *Level and Trends of Contraceptive Use*, 1989.

It is not known how many LDC women currently rely on LAM for family planning, or for what lengths of time it is used in various countries. The Institute has arranged for upcoming demographic surveys to collect more specific data in order to provide this information.

7.2.2 Who Uses NFP? Why Do They Use It, How Do They Use It, and Why Do They Stop?

Women who have ever used NFP (mainly calendar rhythm) tend to be better educated than other women. Religion does not seem to be an important determinant of NFP use in most LDCs. Among the 12 countries studied, religion was a factor only in Liberia, and to a lesser extent Trinidad and Tobago, where Catholics and other Christians are more likely to use NFP; and in Sri Lanka, where there was also a slight positive association between Buddhism and the use of NFP. Several studies have found that medical safety, absence of side effects, and dissatisfaction with other methods are the main reasons people choose to use NFP.

NFP providers in several American cities have indicated that there are Black Muslims among their clientele. It may be useful to investigate whether there is a subset of people who are part of the Islamic religion or culture who are particularly attracted to the use of NFP.

Women included in the surveys identified ineffectiveness as the chief problem with NFP. Method failure was the most frequent reason for discontinuing use of the method. Stopping in order to become pregnant was the second most common reason for discontinuation, followed by concerns about the infrequency of sex and opposition from the woman's sexual partner.

Survey data show that many women who are "using NFP" use "an additional method during the same month"; this is true for about one of every two NFP users in Thailand, the Philippines, and Trinidad and Tobago; one of three in Sri Lanka, and one of every four NFP users in Morocco, Brazil, Colombia, the Dominican Republic, and Peru. Since NFP requires periodic abstinence and does not allow for the use of other methods, these findings show that many LDC women use calendar rhythm, and perhaps other NFP techniques, as means of fertility awareness and are not really practicing NFP.

7.2.3 How Widespread and Useful is Knowledge of Fertility Awareness?

In 12 of the countries covered by these demographic surveys, knowledge of the fertile period ranged from a low of 7 percent in Liberia to a high of 64 percent in Peru. Women who have ever used periodic abstinence have much greater knowledge of the fertile period as compared to other women. This was true even when the data were controlled for the women's educational levels. However, more highly educated NFP users were more likely than less well-educated NFP users to identify the fertile period correctly.

7.2.4 Short-term Continuation Rates and Use of NFP During Various Segments of a Woman's Life

The director of an NFP program in the Washington, D.C. and Maryland area reports that about 70 percent of newly trained couples are still using the method at the end of one year; a program in Zambia reported a 77 percent one-year continuation rate. However, in one project in Peru, 30 of 42 new users (71 percent) dropped out during the first year. As with any family planning method, continuation depends on factors related to client selection and motivation,

as well as the quality of the service (in this case, training and support) provided to the users. One-year pill continuation rates are between 40 and 50 percent in many LDCs.¹²

Little or no data are available to document how LDC women use NFP and fertility awareness throughout their reproductive lives; e.g, what methods people use first, what they move to if they do not like their first method, and which methods they use at different periods of their lives. Although some Western NFP teachers feel that the best NFP users are couples who use it as their first and only method of contraception, the necessity for abstinence probably makes NFP unattractive to most young and newly married couples. LDC women are most likely to use NFP as a way to space their children. Perhaps because they do not trust its effectiveness, they are less likely to rely on it to limit their final family size.

Although a post-partum sequence of LAM followed by NFP seems logical and attractive, findings from early Institute studies are somewhat discouraging regarding the efficacy of NFP techniques as a way to predict the first post-partum ovulation. In addition, because of endocrinologic changes associated with lactation, it is harder for breastfeeding women to learn NFP techniques.

Modern NFP methods (which are based on ovulation) but not calendar rhythm (which is based on menstruation) could be especially appropriate for women who are nearing menopause. Such women have irregular menses, long intervals of infertility, and are more likely than younger women to have medical contraindications for the use of pills. Since they ovulate infrequently, they could practice NFP while observing relatively few and short periods of abstinence and would be otherwise free of the need to contracept.

7.3 Service and Cost Considerations

High-standard teaching of modern NFP methods is labor intensive, time consuming, and thus expensive. The coordinator for the Pittsburgh component of the Title X Program (federally funded family planning services) says that it takes a two-week course, including 4 days of didactic instruction, to train an American family planning nurse practitioner to be an NFP instructor. He also reports that Title X does not consider NFP to be cost-effective and therefore will not pay for it. The woman who heads the NFP-provider organization serving Washington, D.C. and Maryland says that NFP teachers need to have experience with 36 "months of exposure" during their training, i.e., to manage 9 clients for 4 months each, or 4 clients for 9 months each, or 6 clients for 6 months each, etc. She also teaches fertility awareness at Catholic high schools in the D.C./Maryland area and says that she can accomplish her goals for those classes in a one-and-a-half hour session, followed by a question-and-answer period which is scheduled for three months later.

So far, most NFP programs have been run by volunteers. At any one time, each volunteer can handle from 10 to 12 couples who are learning the method. The instruction of a new couple starts with a two-hour session, which is followed by two or three more visits which may be of varying lengths depending on the couple's problems and progress. Unfortunately, very little is known about the people who volunteer to be NFP teachers in varying societies and under different circumstances; it is important to know who they are, why they volunteer, how many couples they can handle at a time, how long they can be expected to stay on the job, and what

¹²Personal communication from Dr. James Shelton, Director, Research Division, Office of Population, U.S. Agency for International Development.

influences them either to continue or stop. NFP instructors in the D.C./Maryland area teach for an average of three to four years, although some continue for a longer time.

NFP programs do not require the back-up of an expensive (and often absent) system for providing medical care, and do not rely on continuing access to supplies, except for basal body temperature thermometers. They require education and outreach, both of which are susceptible to innovative techniques related to communications technology, including radio and the use of videos.

It is assumed that most of the cost of providing NFP is front-loaded, and that, once learned, NFP is available when needed and without cost. However, it is not known how well the information is retained or how much continuing support is needed by couples who use NFP. The costs of NFP over the sexually active reproductive lifetime of a woman should be examined. Pen and paper charts and thermometers are the only material resources used on a continuing basis in most programs. If a home test kit to detect ovulation were available and used, it would increase costs and also require programs to begin to deal with the logistical problems of reagent resupply.

Efforts to promote and support LAM have costs but will be more efficient if conducted in conjunction with other maternal and child health programs. Promoting LAM only requires efforts to prevent the loss of a culturally accepted behavior. This should be easier, and therefore less costly, than promoting a method which requires people to adopt a new behavior.

7.4 Health Advantages and Risks

Although the health risks associated with contraception are small relative to the risks from pregnancy and childbirth, many women believe, for example, that pills are much riskier than they really are. Many women fear them and do not like their side effects. "Risks," fears, and side effects are serious barriers to the wider use of many contraceptive methods. The lack of these risks and fears appears to be the factor which attracts most users to NFP.

Aside from the Institute's current study (discussed in Section 4.4.3) to determine whether pregnancies that occur during the use of NFP are associated with increased rates of spontaneous abortions or of liveborn infants with external anomalies or low birthweight, no other causes of ill health associated with the use of NFP are being investigated. There are, however, some obvious possibilities.

The most obvious possibility is that persons who use NFP may become exposed to sexually transmitted diseases (STD) including AIDS, because they are not using condoms. This, of course, is a risk which may be associated with the use of any method other than condoms; it is not unique to NFP. It becomes a special issue with NFP, however, because NFP "rules" preclude concurrent use of another method. Although this issue is being discussed within the NFP community, there is a tendency to dismiss its importance because most current NFP users are relatively well-educated people who have stable marriages and are members of a church. These characteristics are faint protection against the spread of STDs; the risk must be taken seriously. The fact that many people who use "NFP" also use another method implies that there is an easy solution to the problem. However, although that may be true for most users, to many NFP providers (the volunteers who teach NFP and run NFP programs) the use of a second method vitiates the underlying purpose and central principles involved in NFP. This is an issue which will have to be dealt with more openly, especially since the Institute is trying to make NFP available to a wider group of people and is working in some countries which have a high and rising prevalence of human immunodeficiency virus (HIV) infection. Little or no research has been done on the sexual activities of husbands while their wives are practicing NFP. It has been argued that NFP results in diminished promiscuity and could therefore reduce societal risks associated with

STDs, including AIDS. Data which show greater marital harmony among couples who use NFP cannot demonstrate a causal effect; such differences probably result from factors which influence the self-selection of some couples to use NFP. In addition, if it were not for the fact that NFP has been mainly used by better educated and more happily married couples, one member of the evaluation team would worry that the attempt to promote NFP might result in a higher incidence of physical abuse of wives in some societies.

The Institute is also conducting studies to examine possible nutrition and other health effects of breastfeeding and LAM on both the mother and the baby. Early data suggest that LAM may have an effect on the mother's calcium stores. The health benefits of breastfeeding for infants are well known.

8. Recommendations

8.1 Recommendations for the Remainder of the Current Project

8.1.1 Project Administration

The Institute was reorganized in July of 1989. This reorganization was based on advice from a management consultant and followed widespread recognition of previous administrative problems. The reorganization has resulted in several important improvements in administration of the project: the principal investigator for the project is giving it more attention; executive committee meetings are being held more regularly and are more productive; lines of authority are clearer; and communication has improved. All parties believe that the project is functioning more effectively now, and most of the staff are happier. Not enough time has passed to assess the performance of the Institute as reorganized. Therefore, no recommendations regarding the organizational structure of the Institute during the remainder of the current cooperative agreement have been made.

1. Summary minutes of weekly GU project staff meetings should be prepared on the same day as the meeting and faxed to LARFPC, PITT, IFFLP, and the A.I.D. CTO.
2. The Institute should move as quickly as possible to hire a full-time professional associate to assist the director of the Division for Breastfeeding and provide an additional secretarial position for that division.

8.1.2 Scope of the Project's Focus

The Institute should broaden its view of the mission of the NFP project: it should investigate the potential for interest in NFP among cultural groups that have not previously been involved, and should focus on calendar rhythm as well as modern NFP methods and on fertility awareness as a body of information and skills that are of use to most women, not only to NFP users.

3. Although calendar rhythm may not be the most effective NFP method, it is the one most widely known and practiced. Because it will take a long time to develop many sites able to provide high quality NFP services to LDC women, the Institute should study the use of calendar rhythm, differences and similarities between people who use calendar rhythm as compared to those who use modern NFP methods, how people learn about calendar rhythm, how they practice it, and how their practice of calendar rhythm could be improved. Are there efficient ways to support and improve the use of calendar rhythm method by people who already seem disposed to use it and who do not have access to better NFP methods? Research should also be done to understand the relationships between use of a calendar method and use of NFP based on cervical mucus and/or basal body temperature, i.e., whether the use of rhythm predisposes and facilitates use of the sympto-thermal methods; how to build training in modern NFP methods on pre-existing knowledge and experience regarding rhythm; how to convert NFP users to more effective techniques without unfairly discrediting the older method for those who may like it and use it well and for those who do not have access to instruction in more modern methods of NFP; and to learn why people prefer to use one method instead of another.

4. During the next two years the Institute should investigate the potential interest in NFP among Islamic groups in North Africa, Asia, and the Near East. (Evidence of interest: Black Muslims are among clients of American NFP service providers; two Muslim organizations have joined IFFLP.) LARFPC might be able to do this without leaving home, since there are large groups of relatively recent immigrants from virtually every LDC right in Los Angeles.

5. Although fertility awareness education is a matter of controversy within the NFP community, the Institute should begin to promote this concept much more actively. Fertility awareness education should not be mainly based in the church (which has been the backbone of NFP movement) or in multimethod family planning delivery organizations, but in community organizations, women's organizations, and educational organizations. Communication technologies, such a radio and videos, should be considered.

8.1.3 Peer Review of Proposed Research

6. The Institute should establish clear policies and procedures regarding peer review of proposed research. The Institute conducts and supports a wide range of evaluation and research. Some is very expensive and/or very important and should be held to very high standards. However, operations research, almost by definition, does not require as rigorous research methodology and thus may not need such intensive review. Clear distinctions should be made between project evaluation, operations research, and other research, such as field trials. The expectation for peer review should be formalized, but the review procedures should vary according to the kind of research under consideration.

8.1.4 Biomedical Research

7. The Development and Application of An Enzyme Assay for Estrone Glucuronide. The view expressed by TAG members at their August 1989 meeting that this project should be curtailed and that the principal investigator should be encouraged to consult with industry and other experts to change his assay format to a novel, more simplified format, is a sound one. Although the assay format is not ideal, the investigator has a working system which does not require either a "jug" or an electronic device. This project will provide an early test of the utility of home estrogen tests in the assessment of the fertile period.

8. The Development of Novel Estrogen Tests to Predict the Fertile Period in Women. The Institute should provide support to cover the potential development of assays for urinary estrone glucuronide and pregnanediol glucuronide and for salivary estradiol and progesterone, but not for other non-NFP related applications. In view of the scientific, legal, and commercial complexities of the project, GU should seek ongoing funding and involvement through A.I.D.'s CONRAD project.

8.1.5 Breastfeeding/LAM Activities

9. NFP project money should be focused on efforts related to the contraceptive effects of breastfeeding, and specifically to improving the knowledge, availability, acceptability, and effectiveness of lactational amenorrhea as a method of contraception.

10. The Institute's strategy to promote LAM should concentrate on providing technical assistance to other organizations that support training and/or services related to breastfeeding, child survival and/or family planning in all countries.

11. The Institute should try to incorporate knowledge about LAM into U.S.-based lactation training courses, such as that offered by the University of California, Los Angeles, and into courses for U.S. nurses, midwives and physicians, especially those who are likely to participate in international development work, since they are often looked to as sources of expertise. American and other Western health professionals need to understand not only the importance of breastfeeding for fertility reduction in populations, but also the relative efficacy of LAM as a reliable contraceptive method for individual women. Their support of LAM is necessary in order to instill confidence in this method in LDCs.

12. The Institute should develop a module on LAM which is appropriate to be included in pre-service nursing/midwifery educational programs in LDCs or for continuing education for graduate nurses and midwives.

8.1.6 Collaboration with Other A.I.D. CAs

13. The Institute should resume collection of information about support of NFP, and begin collection of information about support of LAM through other A.I.D. Office of Population CAs, and through the bilateral A.I.D. assistance program.

14. A.I.D.'s Office of Population should inform its CAs that the Agency expects them to continue to support activities related to NFP and breastfeeding programs, and that the existence of the Institute does not diminish the responsibility of other family planning CAs to support and promote this family planning method. The Institute should be more active in seeking opportunities to assist other CAs to incorporate NFP and LAM into their programs.

8.1.7 Use of Graduate Students

15. Because the use of graduate students could increase the number of U.S. scientists interested in conducting research related to NFP, fertility awareness, and LAM, PITT should continue to involve graduate students in Institute projects, and GU should increase its efforts to involve such students.

8.1.8 Dissemination of Institute Research Findings and Other Products

16. More attention and resources should be given to dissemination of the Institute's most important publications and other "products." Certain Institute publications are unique and very important. If the Institute hopes to influence pre-service nursing and midwifery education or to have an impact on ongoing family planning service delivery programs, it should produce its most important documents in very large numbers, and commit considerable thought, energy, and financial resources to distributing those documents. The Institute should identify who needs the information contained in each of these publications, and take a systematic approach to developing mailing lists to meet specific needs. The Institute also needs to pay more attention to the reading level of written materials.

8.1.9 Development of Centers of Excellence

17. The Institute, in conjunction with IFFLP, should identify which LDC NFP programs are or have the potential to be developed into centers of excellence which can serve as models; to be places where others can come for training; to be the home base for LDC consultants; to accumulate good data bases; and to be used for research.

8.2 Recommendations for a Follow-On Project

1. A.I.D. should fund a second NFP project when the current project concludes in 1991. The follow-on project should be implemented through a cooperative agreement rather than a contract. The title of this project should be changed to reflect the expansion of its mission to include fertility awareness and LAM. This is recommended particularly because the definition of NFP restricts that term to family planning methods that rely on periodic abstinence.

8.2.1 Project Structure

2. Because no one institution contains all of the capabilities that are necessary to carry out this complex project, it will probably be necessary to involve at least two, and possibly three

or more organizations in the follow-on project. The legal relationships between the organizations which agree to work together on the project should be subcontracts between the lead organization and the other major collaborators. These subcontracts should be for major areas of work and should ensure that the major subcontractors participate in establishing the project's major strategies, priorities, work plans, and budgets; that the major subcontractors are represented on the project's Management Committee, and that they are recognized as inherent parts of the project, e.g., by being named in project publications, etc. In addition, the subcontracts should provide the major subcontractors with autonomy over their internal administration so long as their work products meet requirements of their contract with the primary contractor.

3. Although IFFLP should not be considered an inherent component of the project, its participation is essential and should be sought. IFFLP should be represented on the project's Management Committee.

4. The project should be implemented through two major divisions, one for LAM, and one for NFP and fertility awareness. All projects and major activities should come under one of these divisions. Even when the two divisions collaborate on projects, primary responsibility for the project should be assigned to one division. Thus, responsibility for the project's main work would be borne by the two division directors. Because of the importance of the division director positions, heads of all organizational components should have a voice in determining who fills these positions. Each division should develop a five-year strategy which specifies realistic long-term goals and objectives. These plans should be developed in concert with A.I.D., and should provide direction for the entire project. The two major divisions should be directed from the lead organization.

5. In addition, the follow-on project should include several functional units, each of which should contribute to the work of both of the two main divisions. Much of the actual project work would be conducted through these units. Division directors should delegate responsibility for managing specific projects to the most appropriate functional unit. Some of the functional units should be located at the lead organization and some should be sited with the major subcontractors, with IFFLP, or even with subcontractors which are not inherent components of the project. There could perhaps be as many as nine functional units, one for each of the distinct types of work that will need to be performed to fulfill the objectives of the two divisions. The actual number of units could be less if some functions were combined into a single unit, so long as the importance of each of these distinct kinds of work is recognized. If there were nine, they would not be of equal weight and significance. The nine possible functional units are as follows:

- Behavioral Science
- Biomedical Research
- Demographic Research
- Evaluation and Operations Research
- Field Trials
- IEC and Outreach
- Resource and Dissemination Center
- Services Development and Support
- Training

The Behavioral Science Unit. This unit must have staff with experience in psychosexual research. Since the behavioral science research that is most needed deals with sexuality and cooperation between sexual partners, the project could look to AIDS researchers for a community of behavioral scientists with the appropriate background to study psychosocial aspects of NFP. The behavioral science arm of the project should focus not only on female NFP users, but also on their husbands and on volunteer NFP teachers.

The Biomedical Research Unit. There is a continuing need for research to broaden the scientific base for NFP and LAM. This unit should conduct clinical and "bench" science studies in-house and through subcontracts with other research institutions. Its main focus would be on the physiology of fertility and of lactational amenorrhea. In addition, it would try to identify chemical changes which can serve as early indicators of impending ovulation and/or which signify that ovulation has occurred, and which could be used as the basis for an inexpensive and easy-to-use product by which women could accurately predict and/or document their own ovulation. However, the development, testing, and/or marketing of products should be subcontracted to another organization.

The Demographic Research Unit. This unit could be at a university, or IRD, which conducts the actual DHS surveys, could be subcontracted to conduct and report the analyses relevant to NFP, breastfeeding and LAM.

The Evaluation and Operations Research Unit. This unit should work in close collaboration with the Training Unit and the Services Development and Support Unit. Evaluation of various approaches to NFP training should be given high priority; LARFPC should develop a list of training variables that need to be carefully examined, including the use of videos, how long it takes to bring a user to autonomy using experiential learning as compared to didactic approaches, and the costs (especially with regard to time) associated with training NFP users. The time given by unpaid volunteer workers should be included in this assessment.

There is also a need to evaluate the effectiveness of second and third generation training that occurs as a result of TOT courses. In addition, the Evaluation and Operations Research Unit should define criteria for a "successful NFP program," as well as for failed programs, and should identify programs in both categories in order to study why programs fail and how they succeed. This unit should evaluate different strategies to integrate LAM into family planning and child survival programs, how to integrate NFP into multimethod family planning programs, and how NFP should be approached in societies in which there is a significant prevalence of the acquired immune deficiency syndrome (AIDS). The project should explore how the University of Pittsburgh's computerized NFP data base and ability to analyze data from NFP user charts can be used to evaluate specific NFP services and to compare the effectiveness of various training methods.

The Field Trials Unit. This unit should be responsible for those studies designated as clinical or field trials. There must be clarity between which projects are field trials and which are operations research. The over-riding purpose of field trials should be to support the development of an approach or approaches to NFP that are effective but require shorter periods of abstinence. The relationship between effectiveness and continuation should also be assessed through field trials. Because the effectiveness of NFP depends on human behavior, and instruction (training) is the means which is used to achieve the desired behavior, the training used in field trials must be carefully defined and controlled. Thus, the Field Trials Unit should work in very close collaboration with the Training Unit.

The IEC and Outreach Unit. The current Division for IEC, at GU, is functioning well and should be the model for this unit in a follow-on project.

The Resource and Dissemination Center. This unit should be seen as a more important unit than is currently the case. Adequate dissemination of Institute documents will require consistent attention and significant resources.

The Services Development and Support Unit. This unit should be responsible for all efforts related to the development and support of NFP organizations, including management training, which should be as practical as possible.

The Training Unit. This unit should review the results of all research done to date, and of the summary of behavioral research that was done at PITT, in order to glean ideas on how to improve training. For instance, studies show that many clients know nothing about the physiology of reproduction and are misinformed about how NFP methods actually work. Users say they are attracted to NFP because of its safety and lack of side effects, and the spontaneity of intercourse on safe days. However, they often do not understand the difference between method effectiveness and use effectiveness, and those beginning to use the method do not realize how much motivation is necessary for effective use. Such findings suggest that NFP users should be taught about the variability in the risk of pregnancy during the "unsafe period," i.e., that the risk is lowest at the beginning and end of the period and highest during the middle. Users might then limit risk-taking to the early and late phase. Research findings also suggest that programs should devise strategies to maximize husbands' participation in NFP training, and should develop instructional materials aimed at husbands.

6. The present TAG should be disbanded at the completion of the current cooperative agreement. It should be replaced with an advisory committee of approximately 10 members who would meet annually. The role of this committee should be to assess the direction of the project's activities and the priorities and qualities of these activities in the context of the stated aims of the project and to advise the principal investigator and the A.I.D. CTO accordingly. This advice, and any specific recommendations, should be provided by the TAG in the form of a brief report, following the completion of each meeting. The chair of the committee should be appointed from among its members, unlike the present arrangement whereby the principal investigator of the Institute chairs the meetings.

7. The project should be led by a project director whose primary work is the overall direction of the project. The project should be supported by an administrator.

8. There should be a Management Committee which meets quarterly. It should include the project director, the directors of both divisions, and representatives of the major subcontractors and of IFFLP.

8.2.2 Use of Project Resources

9. Sixty percent of the follow-on project's programmable resources should be devoted to work related to NFP and fertility awareness; 40 percent should be devoted to work related to LAM. Approximate proportions of funds to be used to support the activities of each functional unit should be determined during annual meetings between the A.I.D. CTO for the project and the Management Committee and should be based on annual work plans. It can be expected that these proportions will vary from year to year, depending on the natural flow of work, on progress within the various areas of research, and on opportunities which may arise during the latter years of the contract based on earlier success.

Appendices

Appendix A
Evaluation Scope of Work

Appendix A

Evaluation Scope of Work

I. EVALUATION PLAN

A. Type: Midterm

B. Purpose

The Cooperative Agreement with Georgetown is scheduled to end in September, 1991, extended from the initial completion date of September, 1990 without an increase in Cooperative Agreement total costs. During the next 12 months, ST/POP should decide whether to continue funding a separate project devoted to promotion of natural family planning, including methods based on periodic abstinence (PA) and breastfeeding (BF) as means of fertility control, or to integrate these activities into other projects.

This evaluation will examine what the project has done to date in response to its stated purposes and priorities. Additionally, the evaluation will look at how the project is implemented.

Questions exist regarding the best combinations of elements and sub-elements. Should periodic abstinence methods and breastfeeding methods (lactational amenorrhea) be separate or together? Should biomedical research be part of the same or a different project as the elements which support service delivery and applied research? Should a project devoted to the delivery of NFP and/or breastfeeding services and evaluation be developed?

This evaluation will permit ST/POP to seek recommendations on these overarching issues as well as the issues of project implementation which can affect the final years of this project.

This will be the first evaluation of this project and Cooperative Agreement, and is now planned to be the sole evaluation prior to the end of the agreement.

C. Use of Findings

1. To comment on project accomplishments and to recommend changes in the current portfolio of activities under this Cooperative Agreement;

2. to recommend improvements in management and administration of the current Cooperative Agreement; and

3. to provide direction for ST/POP in designing activities for follow-on efforts in NFP and breastfeeding.

D. Issues

The issues to be examined fall into two major groups, those related to priorities, or what the project is doing or should be, and those related to process, or how the project is doing its business.

1. Issues relating to Project Priorities

a. Project Contribution to A.I.D. Population Program

This project is one part of A.I.D.'s efforts to provide couples in A.I.D.-assisted countries with a wide range of family planning technologies from which to make an informed and voluntary

choice. Has this project, as implemented, increased the availability of natural family planning methods (those based on periodic abstinence and breastfeeding) to couples in A.I.D.-assisted countries?

b. Project Purpose

Is the purpose of the NFP Project as designed (to improve the knowledge, availability, acceptability, and effectiveness of natural family planning in the less developed countries) still appropriate as a means to contribute to the agency's objective of making a broad range of family planning methods available to couples who wish to voluntarily control the number and spacing of their children? Does this purpose enable the project to respond to the principal concerns of family planning program managers, especially ST/POP-funded CAs, such as effectiveness, costs, and continuation rates of natural family planning methods? Could it be changed in a follow-on project to better address the objectives of A.I.D. in this area? How?

c. Project Content

This project has included both methods based on periodic abstinence and on lactational amenorrhea as means of family planning. Is this an appropriate grouping? Should it be continued, expanded, or reduced?

This project divided efforts into biomedical research; social science research; operations research; information, education, and training; technical assistance; and other NFP activities. Recently, the project staff and program was reorganized to focus on three broader areas: biomedical research regarding identification of the fertile period; breastfeeding, or lactational amenorrhea; and periodic abstinence methods. The latter two areas focus on research and support for service delivery. Is this design combining service delivery and biomedical research appropriate?

d. Priorities between Project Elements

In the Cooperative Agreement, guidelines were established for relative priority among project elements as follows.

- 1) Research (45%)
 - a) Biomedical (20%)
 - b) Operations (15%)
 - c) Social Science (10%)
- 2) Information, Education, and Training (25%)
- 3) Technical Assistance (20%)
- 4) Other NFP Activities (10%)

Were the elements and proportions appropriate? What level of effort has been devoted to each of these project elements? Have changes from these guidelines contributed to achieving the project purpose? To the objectives of ST/POP in conducting this project? Among the "Other NFP Activities", the project staff have functioned as a technical resource for A.I.D. on NFP and BF issues (carrying out meetings and conferences, collecting and disseminating budget and other information, and making presentations at scientific meetings). Has this role required that elements 1-3 above be reduced?

e) Priorities within Project Elements

Priorities were articulated in the Request for Applications, the Cooperative Agreement, and recent Semi-Annual Reports.

The Request for Applications and the Project Description attached to the Cooperative Agreement indicates that priorities will be determined and ranked by the Technical Advisory Group (p. 17). In addition, it provides illustrative biomedical research questions and potential projects (p. 2). For operations research, no priority research questions are mentioned, but improvements in the effectiveness of NFP services and testing operational effectiveness of program interventions are functions to be served; NFP programs are used to illustrate the description of operations research methodologies (pp. 5 ff). An illustrative list of five project areas/questions in order of priority is provided for Social Science Research (pp. 9-10). Three foci are listed for Information, Education, Communication, and Training programs, and detail is provided regarding activities expected (pp. 10 ff). Illustrative categories for Technical Assistance are listed (p. 14). Similarly, illustrative types of activities are listed (pp. 16-17) for Other NFP Activities.

Recent Semi-Annual Reports have reported the following lists as "Priority Issues" for each project element.

Biomedical Research

- 1) Predict Ovulation and Determine the Fertile Period
- 2) Assess BV as Child Spacing and Identify BF practices Affecting Fertility
- 3) Assess NFP Methods for Women in Differing Circumstances
- 4) Determine the Relationship between NFP and pregnancy outcome
- 5) Define the duration of the Fertile Period

Social Science Research Priorities

- 1) Identify and Study Psychosocial Factors related to NFP
- 2) Analyze BF Trends and Practices
- 3) Describe Cross-National Prevalence of NFP Use
- 4) Study NFP and BF as child spacing methods

Operations Research

- 1) Identify the Impact of Structural and Operational Factors on NFP and BF Programs
- 2) Assess/Evaluate NFP delivery systems, teaching/training, and BF programs

Education, Communication, and Training

- 1) Improve quality and availability of NFP and BF training and materials
- 2) Enhance availability of educational materials on NFP and BF
- 3) Increase the acceptability of NFP and BF
- 4) Maximize appropriateness and effectiveness of NFP and BF education and outreach
- 5) Improve management and outreach capability of NFP providers

Service Delivery Support

(This is a project element consolidated in the last year, and does not appear in previous documentation.)

- 1) Assist NFP programs to collect data useful for management and reporting
- 2) Support the delivery of high quality NFP and BF services

Other NFP Activities

(No specific priority issues were identified for this element.)

Do these priorities correspond to the priorities established early in the project? If so, are they still appropriate? If not, by what process were they changed, and do they better serve the project purpose and goal than the initial priorities? How has the selection of activities responded to established priorities? Has the designation of priority issues or selection of project activities responded to findings from research and service delivery experience during the course of the project? Should they continue as priority issues?

2. **Process Issues**

a. **Project Resources and Allocation**

Given the project's purpose and the priorities selected by the Institute, have funding levels been adequate?

Have resources, including sub-agreement funds, staff (including support staff), and equipment, been distributed between project elements as originally envisioned? Between priorities within elements? Should adjustments be made now in the relative emphasis between elements, or between priority issues within them?

Is the Institute staff appropriate re: technical specialties, professional to support staff ratios, regional experience mix, and language mix? How should the mix and allocation of such resources be determined for follow-on projects?

b. **Technical Advisory Group**

Is the TAG performing its intended roles, which were defined in the Cooperative Agreement: to assist in the determination and ranking of priorities, to advise the Recipient and the CTO, to assist the Recipient in developing projects (called activities in this scope of work for clarity), to review proposals and recommend changes, to monitor project activities, and to provide general assistance as requested? What role has the Technical Advisory Group actually played? Has the TAG been too focused on individual sub-projects, as compared to the general directions of the project? Would it make sense to have separate TAGs for 1) biomedical, breastfeeding, and periodic abstinence programs; or 2) for Biomedical; Information, Education, Communication, and Training; and Operations Research and Social Science; or 3) some other grouping?

c. **Activity Selection**

How were activities generated? Were they developed in response to project priorities both among and within project elements? How can priorities best be adhered to in selecting and developing activities?

d. **Activity Development**

How long did it take to develop sub-projects? What could be done differently in the future to reduce the elapsed time in moving from concept to implementation of activities?

e. **Research Designs**

What process was used to establish research designs during the project? Were appropriate designs chosen? Were they implemented as designed? Were changes consistent with the sub-project purposes? Should changes be made in sub-project development, approval, and implementation processes with host country institutions? Could any of these changes be effective in the current agreement?

f. **Relationship to Other Family Planning Organizations**

How does the Georgetown Institute relate to other family planning organizations, both A.I.D.-funded and not? Is the Institute used as a resource, especially by A.I.D.-funded CAs including family planning service providers? Is the Institute a resource for other international family planning donor

or research organizations, such as IPPF or WHO? What changes could improve the impact of this project on family planning service providers, donors, and research organizations?

g. Institute Structure, Management, and Administration

This project is implemented by a Cooperative Agreement with Georgetown University. Georgetown, along with two sub-recipients, the Los Angeles Regional Family Planning Council (LARFPC), and the University of Pittsburgh Graduate School of Public Health, form the Institute for International Studies in Natural Family Planning, which is commonly referred to as the Georgetown Institute. How has this organizational structure of the Institute affected the responsiveness of the Institute to initial project priorities between and within elements, the development of project activities, and activity implementation? Is there a clear chain of command and operating procedures to promote the accomplishment of the project? Is distribution of resources (money, personnel, authority) appropriate between Institute members to carry out remaining project activities?

Changes were made in July 1989, redefining project responsibilities at Georgetown and reporting relationships between LARFPC and Pittsburgh and Georgetown. Have these improved operating efficiency and effectiveness?

Would the project be better served by a sub-project specific sub-agreements with other U.S. organizations rather than the present Institute arrangement?

h. Georgetown University Administration of this Agreement

Does the administration of this project by Georgetown University beyond the Institute facilitate or hinder project implementation? Are there actions which could be taken by the project staff in dealing with University administration to make implementation more efficient?

i. A.I.D. Monitoring

Has A.I.D. (including CTOs, ST/POP, Procurement Office, and Financial Office staff) monitored this project in a way that promotes or impedes its achievement of priorities between and within project elements? It should be noted that there have been three A.I.D. staff members directly involved with the project throughout its life: the division chief of ST/POP/R, the Natural Family Planning Specialist, and a project manager. Here, the evaluators and project staff are asked to evaluate A.I.D. as an executing and monitoring agency.

Appendix B

Members and Meetings of the Technical Advisory Group

Appendix B

Members and Meetings of the Technical Advisory Group

Dr. William P. Collins
Professor in Reproductive Biochemistry
King's College School of Medicine
London, England

Ronald H. Gray, MD
Professor, Department of Population Dynamics
The Johns Hopkins University
Baltimore, Maryland

Ms. Kathy Kennedy
Senior Research Analyst
Family Health International
Research Triangle Park, North Carolina

Mr. John Kweri
Manager, Information and Planning Project
Ministry of Health
Nairobi, Kenya

Claude Lanctot, MD
Executive Director, IFFLP
Washington, D.C.

Sister Mary P. McCarthy, PhD
Associate Director, Catholic Charities
Los Angeles, California

Kamran S. Moghissi, MD
Professor, Division of Reproductive Endocrinology
and Infertility
Wayne State University/Hutzel Hospital
Detroit, Michigan

Ms. Margot Zimmerman
PIACT/PATH
Washington, D.C.

Rochelle Shain, PhD
Associate Professor in Obstetrics and Gynecology
University of Texas Health Science Center
San Antonio, Texas

Paul Van Look, MD, PhD
Medical Officer
World Health Organization
Geneva, Switzerland

Technical Advisory Group Meetings

- February 1986 - Washington, D.C.**
- June 1986 - Ottawa, Canada**
- November 1986 - Washington, D.C.**
- May 1987 - Washington, D.C.**
- November 1987 - Washington, D.C.**
- June 1988 - Pittsburgh, Pennsylvania**
- August 1989 - Nairobi, Kenya**

Appendix C
Institute Staff

Appendix C

Institute Staff*

Georgetown University

John T. Queenan, MD	20%	Principal Investigator	9/85-Present
Ellen McLaughlin, BSN, MSc	90%	Administrator	11/88-Present
Victoria Jennings, PhD	100%	Director, Applied NFP	9/85-Present
Miriam Labbok, MD, MPH	80%	Director, Breastfeeding	7/87-Present
Michael J. Zinaman, MD	50%	Director, Biomedical Research	9/85-Present
Rosalia Rodriguez-Garcia PHN, MSC	50%	Director, IEC	12/86-Present
Lois Schaefer, BSN, MPH	100%	IEC Associate	1/1/90-Present
Barry Albertson, PhD	30%	Research Associate	9/85-Present
Tom Tomai, BS	75%	Research Associate	7/87-Present
Kristina Stenberg	80%	Secretary IV	8/89-Present
Magaly Penuela	100%	Executive Secretary	1/86-Present
Louise Macura	100%	Secretary IV	2/88-Present
Bea Mantoni	100%	Administrator	10/87-8/88
James Berardo	50%	Administrator	9/85-10/87
Leonor Greenidge-Beadie	100%	Account Analyst	4/88-9/89
Cynthia Lindsey	100%	Account Analyst	9/87-4/88
Solanges Smrcka	100%	Sr. IEC Specialist	12/85-9/86

University of Pittsburgh

Ed Ricci, PhD	35%	Social Science Research Director	10/85-Present
Thomas Schorr, PhD	50%	Project Manager	1/89-Present
Ravi Sharma, PhD	70%	Senior Social Scientist	10/85-Present
Gilberto Ramos, MS	50%	Data Analyst	12/87-Present
Susan Merriman	100%	Administrative Assistant	6/89-Present
Renae Brinza	100%	Administrative Assistant	10/85-7/86
Ken Jaros, PhD	20%	Project Manager	10/85-5/89
Howard Rockette, PhD	10%	Data Center Director	10/85-9/88
Cheryl Young	100%	Administrative Assistant	7/86-8/87
Fritz Adkins	100%	Administrative Assistant	8/87-1/89
Mary Ann Sevick	50%	Graduate Student Researcher	10/85-5/87
Susan Stranahan	50%	Graduate Student Researcher	1/86-9/87
Nancy Obuchowski	50%	Graduate Student Researcher	1/87-9/88
Thirumani Panchalingam	100%	Research Specialist IV	7/88-11/89

Los Angeles Regional Family Planning Council

Kimberly Aumack, BA	100%	Training Director	10/85-Present
Diane Vogelsang, BA	50%	Associate, NFP Trainer	10/85-Present
Karen Wade, RN, MA, CLC	50%	Associate, Lactation Consultant	12/88-Present
Gloria Mejia, MD	50%	Associate, NFP Trainer	12/88-Present
Maria Mejia	100%	Secretary	2/86-Present
Elisa Munoz	50%	Principal Associate, NFP Trainer	10/87-3/88
Ron Frezieres	25%	Fiscal Contract Manager	10/87-9/88
Barbara Kass-Annese, RN, CNP	50-75%	Director	10/85-7/88
Laurie Goodman	50%	Associate, NFP Trainer	4/86-6/87

- C-2 -

Angel Martinez	100%	Director	2/88-8/88
Gerry Escalona	25%	Accountant	10/85-1/87

*Percentages of time/effort for many of the personnel listed have fluctuated over the project period. The most recent applicable percentage is listed above.

Appendix D

Current or Recently Completed Biomedical Research Projects

Appendix D

Current or Recently Completed Biomedical Research Projects

1. The development and application of an enzyme assay for estrone conjugate: phase II.
2. The development of novel estrogen tests to predict the fertile period in women.
3. Validation of Dr. J. B. Brown's pregnanediol-3-glucuronide enzyme assay.
4. Evaluation of milk progesterone levels by calorimetric assay: comparison with plasma progesterone by RIA.
5. Does urinary creatinine normalization improve the ability to predict the day of ovulation in normal menstrual cycles using estrone glucuronide and pregnanediol glucuronide.
6. Pulsatile GnRH in lactating women (funding support from NIH).
7. Calcium metabolism in lactating women (funding support from NIH).
8. Multiple study of NFP among women.
9. The efficacy of the sympto-thermal method of NFP in lactating women after the return of menses.
10. The relationship between NFP practice and pregnancy outcome.
11. The physiology of sperm recovered from the human cervix, acrosomal status and response to inducers of the acrosome reaction: sperm mucus interactions.
12. Follicle regulating protein and the return of ovarian function during hyperprolactin amenorrhoea.

Appendix E
Institute Publications

INSTITUTE PUBLICATIONS PORTFOLIO

(August - 1989)

CODES:

PRJ= Peer Review Journal
 IP= Institute Publication
 IR= Institute Issue Report

IMP= Intramural Projects
 EMP= Extramural Projects (subcontractors)

BIOMEDICAL

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination:	Budget	Point Person
Completed						
1. The Prediction of Ovulation and monitoring of the fertile period.	Researchers	PRJ (NFP)	multiple	"Advances in Contraception" Institute	IMP 1987	Albertson
2. Non-Radiometric Assays (NIH/GU)	Researchers	Book (NFP)	multiple	Publisher: Alan R. Liss, Inc., New York	IMP 1988	Albertson
3. Constituents of Saliva and breast milk	Researchers	PRJ (BF)	multiple	"Int. J. of Gyn/Ob." Institute	IMP 1989	Albertson
4. Sperm Survival and Acrosomal status (Accepted for publication)	Researchers	PRJ (NFP)	multiple	"Biology of Reproduction" Institute	IMP	Zinaman
5. Calcium Metabolism in Lactation	Researchers	PRJ (BF)	multiple	Publisher	IMP Submitted 10/89	Zinaman
6. Pregnancy Outcome Associated with NFP: Scientific Basis and Experimental Design for an International Cohort Study	Researchers	PRJ	multiple	"Advances in Contraception"	IMP 1988	Zinaman/Jennings
7. The Inhibition of Human Adrenal Steroidogenic Enzyme Activities by Suramin	Researchers	PRJ	multiple	J. Clinical Endocrinol. Metab.	IMP 1989	Queenan/Albertson

Institute Publications

Appendix B

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
8. Enhanced Follicle Regulatory Protein (FRP) Levels Accompany Reinitiation of Ovulatory Function after Parturition (Accepted for publication)	Researchers	PRJ	multiple	The Endocrine Society	IMP 1989	Albertson/Tomal
In Process						
1. Creatinine/No Creatinine	Researchers	PRJ	Multiple	TBD	EMP	Zinaman
2. Ovulation Induction in Lactating Women	Researchers	PRJ (NFP/BF)	Multiple	TBD	IMP	Zinaman/NIH
3. Neuroendocrine Mechanisms of Lactation-Induced Amenorrhea	Researchers	PRJ (NFP/BF)	Multiple	JAMA	IMP	Zinaman/NIH
4. Breastmilk Pumps	Researchers Lactation Managers	PRJ (BF)	Multiple	TBD	IMP	Zinaman
5. Use of NFP during Lactation	Researchers Lactation Managers NFP Educators	3-5 PRJ (BF/NFP)	Multiple	TBD	EMP	Zinaman/Labbok
6. Development and Application of an Enzyme Assay for Estrone Conjugates (CA/Davis)	Researchers	PRJ (NFP)	Multiple	TBD	EMP	Albertson
7. Prediction of Fertile Period (Israel)	Researchers	PRJ (NFP)	Multiple	TBD	EMP	Albertson
8. Algorithm for Peak Detection in Normal Cycles	Researchers	PRJ (NFP)	Multiple	TBD	IMP	Zinaman
9. Application to Urines from Menstrual Cycles	Researchers	PRJ (NFP)	Multiple	TBD	IMP	Zinaman

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
Planned						
1 Multicenter Study (FHI)	Academics/ program	PRJ (BF/NFP)	Multiple	TBD	EMP	Zinaman
2 Efficacy of ST	NFP Scientists/ Researchers	PRJ (BF)	Multiple	TBD	EMP	Zinaman
3 PDG in Young Girls Entering 1st Fertile Period (Cutler & Albertson, NIH)	NFP Scientists/ Researchers	PRJ (NFP)	Multiple	TBD	IMP	Albertson
4 Implications of Biomedical Findings for NFP Teaching*	NFP programs/ teachers	IP (NFP)	500	TBD	IMP	Zinaman

*Requires Concept Paper

BREASTFEEDING

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
Completed						
1. BF Promotion in Mexico	Educators BF programs	Bulletin	Multiple	"APHA" M and C	IMP 1988	Rodriguez
2. The Lactational Amenorrhea Method	Educators BF programs	Bulletin	Multiple	"APHA" M and C	IMP 1988	Labbok
3. BF and child spacing	BF/CS programs	Booklet	500 Needs Reprinting	WHO/FHI Institute	IMP 1988	Jennings/ Labbok
4. A community-based approach to the promotion of BF	BF/CS programs	PRJ	Multiple	"JOGN"	IMP 1990	Rodriguez
5. Breastfeeding: Passport to Life (a) BF and FP: A Vital Complementarity (b) BF and Working Women	Educators BF, CS, FP programs	Book	(a) 200 (b) multiple	UNICEF/NCIH	IMP 1989	(a) Labbok (b) Rodriguez
6. "BF Packaged Response"	General Educators	Existing BF materials	50	Institute	IMP 1987	Rodriguez
7. Cost Effectiveness Analysis	OR researchers BF programs NFP programs	IIR#2 PRJ (In process) brief (In process)	750 PRJ PRJ	TBD TBD TBD	IMP IMP IMP	Labbok/Krasovec Labbok/Krasovec Labbok/Krasovec
8. BF Guidelines for FP and CS Programs	FP program Directors policy makers BF programs	IP Guidelines 2	2000 English 500 French 1500 Span.	Institute, USAID, CA UNICEF, WHO, Others	IMP	Labbok/Krasovec

14

5/1

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
9. Breastfeeding and Child Spacing: What Health Care Providers Need to Know	Health and FP providers	WHO	Multiple	Institute WHO	staff time	Jennings
10. IF BORN: A Meaningful Acronym	MCH/CS/FP Community	PRJ	Multiple	American Journal of Preventive Medicine	IMP 1987	Labbok
11. Relationship of BF and Modernization Factors to Infant Mortality in Four African Countries	MCH/CS Community	Doctoral dissertation	Multiple	U. of Pittsburgh Institute	IMP 1988	Stranahan
12. Lactancia Para La Salud (Report of FEMAP BF Promotion and Evaluation Program)	BF/CS Community	PRJ	Multiple	Health Sciences Review (U. of Pittsburgh)	EMP 1988	McDonald/Aumack/ Rodriguez
13. A Community Study of a Decade of In-Hospital BF: Implications for BF Promotion	BF/CS Community	PRJ	Multiple	American Journal of Preventive Medicine	1988	Labbok
14. The Development and Use of Graphically Presented Algorithms in Paramedical FP Services	BF/FP Community	PRJ	Multiple	International Quarterly of Community Health Education	1988	Labbok
15. BF Fact Sheet	Wide policy and public relations use	IP	6000	Institute	IMP	Labbok/Wade/ Lovich
16. A Community Based Approach to the Promotion of BF in Mexico (accepted for publication)	BF/MCH Programs	PRJ	Multiple	Journals of Obstetrics Gynecology and Neonatal Nurses	EMP 1989	Rodriguez/ Aumack

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
17. Proceedings: Meeting on Mother's Support Groups	Mothers Support Groups	IGAB 3	~100	Institute	IMP	Labbok
<u>In process</u>						
1. Analysis of DHS data	Countries and policy makers	IP Monographs PRJ	TBD TBD Multiple	Institute Other TBD	EMP/ IMP	Sharma Sharma Sharma
2. Breastfeeding: Protecting a Natural Resource	Policy makers	IP/IMPACT	23,000 Eng. 8,000 Fr. 12,000 Sp.	Institute, CA, USAID, WHO, IMPACT, others	IMP	Labbok
3. BF Definitions	BF researchers/ programs worldwide	IIR#4/IGAB I Guidelines I PRJ	200 1000 Eng 1000 French 1000 Spanish Multiple	Institute, CA, USAID WHO, IMPACT, others	IMP IMP	Labbok/Krasovec Labbok/Krasovec
4. BF Module for Nursing Schools	Health personnel, BF, CS, programs	PRJ Proceedings	500 Multiple	Institute, Latin American Nursing Schools; PAHO network, USAID, CAs others	IMP	Rodriguez/Schaefer
5. BF Policy: NCIH Panel Proceedings	BF policy promoters	IIR	200	Institute, CAs, USAID, others	IMP	Labbok/Krasovec
6. Effect of BF on Child Spacing (Cornell)	Fertility researchers and BF programs	PRJ (Several)	Multiple	Publisher	EMP	Habicht
7. Proceedings, Workshop on BF and Health care	FP, CS programs	IGAB2/Journal Supplement	4000	Publisher, AID, WHO, UNICEF	IMP	Labbok

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
8. Revision "BF Packaged Response"	General, Educators	BF material	PRN (~50)	Institute	IMP	Wade/Labbok
9. Evaluation Techniques for NFP & BF Programs-Process Analysis Handbook	BF, NFP, FP, CS and other	IP	TBD	Institute, other	IMP	Ricci/Labbok/Rodriguez
10. Use of NFP During BF	NFP programs and researchers	PRJ Guidelines 5	Multiple TBD	Institute Institute	IMP IMP	Labbok Labbok
11. BF Technical Skills Essential for Nursing Students	Nursing faculty Students	IP PRJ	TBD Multiple	Institute, others TBD	IMP	Wade
12. BF Sequelae	BF programs researchers	PRJ	Multiple	TBD	IMP	Labbok
13. BF and Safe Motherhood	SM, BF, CS, & FP programs Health program and policy professionals	Monograph PRJ	250 Multiple	Who, World Bank, AID TBD	IMP IMP	Labbok/Krasovec Labbok/Krasovec
14. BF and Malnutrition	BF Health professionals	Guideline 4 IIR	1000 Eng. 1000 Fr. 1000 Sp. ~100	Institute Institute	IMP IMP	Labbok/Krasovec Labbok/Krasovec
15. Obstacles to BF	BF Health professionals	Monograph/ PRJ	500	TBD	IMP	Labbok/Lovich

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
Planned						
1. Evaluation of BF Promotion (FEMAP)	BF programs	PRJ	Multiple	Publisher TBD	EMP	Ricci
2. BF Promotion in the Post-partum Period (Chile)	BF programs researchers	PRJ	Multiple	TBD	EMP	Labbok/ Project Staff
3. Impact of Radio Programs on BF Promotion (Cusco)	IEC, BF and CS programs, educators	PRJ	Multiple	Publisher TBD	EMP	Rodriguez
4. Perception of "Let Down"	BF programs researchers	PRJ	Multiple	TBD	IMP	Labbok
5. Proceedings: Meeting on Lactational Education and Management	BF Education Specialists	IGAB 4	~100	Institute	IMP	Labbok/ Koniz-Booher
6.. W/IO Multicenter Study of BF Patterns	BF programs Researchers	PRJ	Multiple	TBD	EMP	Labbok/ Project Staff
7. BF Secondary Data	BF researchers BF programs	PRJ	Multiple	Publisher	IMP/EMP	Labbok/ Zinaman
8. Lactational Amenorrhea (slide shows)	FP and BF programs	PRJ	Multiple	TBD	EMP/IMP	Labbok
9. Several Pending Articles on Scientific Research	Academics/ programs	PRJ	Multiple	TBD	IMP	Labbok
10. Breastfeeding and Working Women	BF Health professionals	IGAB 5 Guidelines 3	~100 500	Institute	IMP IMP	Wade Wade
11. Impact of LAM in FP Service Delivery (CEMOPLAF)	BF/FP/CS programs administrators	PRJ	Multiple	Publisher	EMP	Wade

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
12. Impact of LAM in CS Service Delivery (Guatemala)	BF/CS programs administrators	PRJ	Multiple	TBD	EMP	TBD
13. Impact of LAM in CS Service Delivery (Honduras)	BF/CS programs administrators	PRJ	Multiple	TBD	EMP	TBD
14. Macroeconomic Model of Valuation of Human Milk	Development policy makers and planners	IP/PRJ	TBD/ Multiple	TBD	EMP	Wade
15. Summary Monograph for IGAB Meeting on BF Strategy*	Policy makers	IGAB	500	IGAB meeting, WHO, AID, UNICEF	IMP	Labbok
16. Does BF Have a Place in FP Programs?*	FP programs/ policy makers	PRJ/ monograph	Multiple	TBD	IMP	Labbok

- E-9 -

* Requires Concept Paper

NATURAL FAMILY PLANNING

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
Completed						
1. Outreach Strategies for NFP	NFP programs IEC	IIR#1	500	Institute IFFLP	IMP 1987	Rodriguez
2. Glossary of NFP Terms	Researchers, educators, trainers	IP	1000 English 500 French 500 Spanish	Institute Request	IMP 1988	Rodriguez
3. NFP Packaged Responses	NFP & FP educators researchers	Resource Center packages	English Spanish	By request Institute	IMP 1988	Rodriguez
4. TOT Alumni Newsletter	NFP trainers	Biannual Memo	40 English 40 Spanish 40 French	LARFPC	IMP 1989	Aumack/ Mejia/ Vogelsang
5. Use of Periodic Abstinence for FP	US Ob/Gyn	PRJ	-Multiple	"Clinical Ob/Gyn"	IMP 1989	Labbok/ Queenan
6. Data Management Guide For NFP Programs (1st Edition)	NFP, FP Programs	IP	English French Spanish	Institute and by request	IMP 1989	Schorr
7. Management and Outreach Resource Materials for NFP Programs	Trainers, managers IEC personnel	IP	English	Institute	IMP 1988	Jennings/ Wade
8. NFP Information Package for Policy Makers	Policy makers, professionals, leaders	IP/IMPACT	2500 Eng. 1500 Sp. 1500 Fr.	Institute TBD	IMP 1989	Rodriguez
9. Cost Effectiveness*	Researchers NFP Programs	IP PRJ	250 Multiple	Institute, UP Others TBD	IMP	Labbok

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
10. Guide for NFP Trainers*	NFP & FP Trainers	IP	500 English 250 French 250 Spanish	Institute TBD	IMP	Aumack
11. Fifth National and International Symposium of NFP	NFP,FP Communities	Proceedings	500	NFP Coalition	Staff time	Rodriguez
12. The Effectiveness of NFP: Studies with Selected Emphases	Researchers NFP/FP Community	PRJ (Abstract)	Multiple	Advances In Contraception	IMP 1988	Labbok
13. A Cross Culture Assessment of Characteristics of Ovulation Method Acceptors	NFP/FP Community	PRJ	Multiple	Studies In Family Planning	IMP 1988	Labbok
14. Factors Related to Ovulation Method Efficacy in Three Programs: Bangladesh, Kenya and Korea	Researchers NFP/FP Community	PRJ	Multiple	Contraception	IMP 1988	Labbok
15. Periodic Abstinence: The "NFP" Methods	NFP/FP Community	PRJ	Multiple	Dialogues In Contraception	IMP 1988	Queenan/ Labbok
16. Contraceptive Technology 14th Revised Edition	FP Community	Book	Multiple	Publisher: Irvington Publishers, Inc. New York	IMP 1988	Labbok
17. A Fertility Awareness and NFP Resource Book	NFP/FP Community	Book	Multiple	Publisher: Small World Publications Corvallis, Oregon	IMP 1988	Rodriguez
18. Introduction of NFP during Lactation: What is the Efficacy?	BF/NFP/FP Community	PRJ Abstract	Multiple	Contraception	IMP 1988	Labbok

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
In Process						
1. Psychosocial Aspects of NFP: A Review of Selected Literature	NFP Programs	PRJ	250	Institute UP, others TBD	IMP	Sharma
2. Longitudinal Study of NFP Use (Philippines)	NFP Researchers	PRJ	Multiple	Publisher	EMP	Labbok
3. Controlled Study of Simplified NFP (Philippines)	NFP Community	PRJ	Multiple	Publisher	EMP	Jennings
4. Analysis of CM/BBT	NFP Community	PRJ	Multiple	TBD	IMP	Rockette
5. NFP for American Family Physicians	Physicians	Monograph/ Other	Multiple	Publisher	IMPP	Labbok
6. Handbook on How to Develop* Outreach Programs. Field-based case studies	NFP & FP program managers, administrators and educators, and IEC staff	IP	200 English 200 Spanish 100 French	Institute Others TBD	IMP/EMP	Rodriguez
7. Report of the Working* Group Meeting on Psychosocial Issues in NFP	NFP, FP Professionals	IIR	200 English	Institute by request	IMP 1990	Schorr
8. Secondary Analysis of DHS Periodic Abstinence Data	NFP policy makers	IP/PRJ	TBD/ Multiple	TBD	IMP	Sharma
9. Periodic Abstinence in Peru	NFP policy makers, researchers	IP/PRJ	TBD Multiple	TBD	IMP	Sharma
10. Quality Indicators in Family Planning Service Delivery	FP providers NFP providers CA, policy makers	Monograph	Multiple	TBD	IMP	Jennings/ Task Force

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
11. Developing Outreach Programs to Increase NFP Client Levels	NFP programs IEC specialists	PRJ	Multiple	Publisher TBD	IMP	Rodriguez
12. Data Management Guide for NFP Programs* (2nd edition)	NFP/FP programs	IP	250 English 250 Spanish 250 French	Institute and by request	IMP 1990	Schorr
Planned						
1. Use Effectiveness and* Continuation in NFP: Issues in Measurement and Current Findings	NFP/FP community	PRJ	Multiple TBD	TBD	EMP	TBD
2. NFP in Multimethod FP Programs*	FP managers Trainers	IP	TBD	TBD	IMP	Jennings/ Aumack
3. NFP Education in Women's Home* Economics Centers: A Client Recruitment Approach	NFP programs	PRJ	Multiple English Multiple French	Publisher TBD	EMP	Rodriguez
4. Impact of Mass Media Campaign in the Recruitment of NFP clients and Increased NFP Use*	Researchers managers IEC personnel	PRJ	Multiple English	Publisher TBD	EMP	Rodriguez
5. Cost Analysis of Group Teaching (Action Familiale)*	Researchers teachers	PRJ	Multiple English	TBD	EMP	Aumack
6. Issues in Working with Education and Health Programs to Develop NFP Services*	NFP/FP programs Educators	PRJ	Multiple	TBD	IMP	TBN

17

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
7. Prospective Study of NFP Acceptors: The Action Familiale Experience*	NFP Programs	PRJ	Multiple	TBD	IMP	St. Mart/ Toma/ Jennings
8. NFP Methods: Issues in Simplification (Xavier University)	NFP, FP Programs	IP	English Institute French Spanish		EMP	TBN
9. Approaches to TOT in NFP*	NFP trainers Instructors managers	PRJ	Multiple	TBD	IMP	Aumack
10. Process, Follow-up, and Outcome of TOT in NFP*	NFP trainers,	IP	TBD	TBD	IMP	Aumack
11. Periodic Abstinence in Sri Lanka	NFP policy makers, researchers	IP/PRJ	TBD/ Multiple	TBD	IMP ^o	Sharma
12. Automation of NFP Management Information System: A Report from the Kenya Catholic Secretariat, Family Life Programme	NFP policy makers managers, researchers, supervisors, trainers	IP(NFP)	TBD/ English	TBD(preferably as a special issue of a PRJ)	IMP	Scorr

10

POPULATION/MCH

Working Titles	Target Audience	Type of Publication	Number of Copies	Dissemination	Budget	Point Person
Completed						
1. Promoting Safe Motherhood	MCH/CS/FP Community	Bulletin	Multiple	Society of International Development	Staff Time 1989	Rodriguez
2. Institution Building Through In-Country Training	Health and development trainers/ educators	Proceedings of the Annual Conference of International Development	Multiple	Society of International Development	Staff Time 1989	Rodriguez

27

Appendix F

List of Persons Contacted

Appendix F

List of Persons Contacted

Office of Population, United States Agency for International Development, Arlington, VA

Duff Gillespie	Director
Carol Dabbs	Research Division, current CTO for the NFP Project
Harriet Destler	Family Planning Services Division, previous CTO for the NFP Project
Jeff Spieler	Research Division, previous CTO, current co-CTO

Institute for International Studies in Natural Family Planning (NFP)

Georgetown University, Washington, D.C.

School of Medicine, Department of Obstetrics and Gynecology

John T. Queenan, MD	Principal Investigator
Victoria Jennings, PhD	Director, Division of Applied NFP
Miriam Labbok MD, MPH	Director, Division for Breastfeeding/LAM
Rosalia Rodriguez-Garcia, PHN, MSc	Director, Division for Information, Education and Communication
Michael Zinaman, MD	Director, Division for Biomedical Research
Ellen McLaughlin, MSc	Administrator
Barry Albertson, PhD	
Ronnie Lovich	Consultant
Lois Shaefer	Consultant
Louise Macura	Secretary
Magaly J. Penuela	Secretary
Kristina Stenberg	Secretary

Office of Sponsored Programs

Ernest Porta	
Lee Jackson	Financial Management

Los Angeles Regional Family Planning Council (LARFPC), Los Angeles

Thomas C. Kring*	Executive Director
Kimberly J. Aumack	Director, Training Division
Ron Frezieres, Manager*	Research Unit and Finance Department
Gloria Mejia, MD	Training Associate
Diane Vogelsang	Training Associate
Karen Wade, RN, MS	Training Associate/Lactation Consultant
Maria Mejia	Administrative Assistant
Terri Walsh*	Epidemiologist
Adrian Davis*	Consultant
Barbara Kass-Annese, RN, CNP*	Consultant
Adrienne Duque	Training Associate

**Member of the LARFC staff but not assigned to the Institute project.*

University of Pittsburgh Graduate School of Public Health, Pittsburgh

Edmund M. Ricci, PhD
Thomas S. Schorr, PhD
Ravi K. Sharma, PhD
Susan Merriman

Social Science Research Director
Project Manager
Senior Social Scientist
Administrator

Persons who are not members of the Institute staff:

Kenneth J. Jaros, PhD
Laura Leviton, PhD
James Newbitt
Howard E. Rockette, Jr., PhD

Assistant Professor (formerly on the staff of the Institute)
Assistant Professor
Senior Research Assistant (ad hoc computer expert)
Professor of Biostatistics (formerly on the staff of the Institute)

International Federation of Family Life Promotion (IFFLP), Washington, D.C.

Claude Lanctot, MD

Executive Director

Technical Advisory Group Members

Milton Corn, MD (member ex officio)
Kathy Kennedy

Dean, Georgetown University School of Medicine
Senior Research Analyst, Family Health International (interviewed by telephone)

Claude Lanctot, MD
Sister Mary Phyllis McCarthy, PhD

Executive Director, IFFLP
Associate Director, Catholic Charities, Los Angeles

Other people interviewed in Pittsburgh:

Frank A. Bonati, DrPH
William A. Uricchio, PhD

President, Family Health Council of Western PA
Professor of Biology, Carlow College, and
Immediate Past-President IFFLP

Other people interviewed in Washington:

Wilma Stevenson

Executive Director of Maryland/District of Columbia
NFP Providers

Telephone Interviews:

National Institute for Child Health and Human Development, National Institutes of Health, Bethesda, MD

Gabriel Bialy, PhD
Jeff Evan

Chief, Contraceptive Development Branch,
Health, Demographic and Behavioral Sciences
Branch

James Lea, PhD

Director, Program for International Training in
Health (INTRAH), the University of North Carolina
at Chapel Hill School of Medicine

Edward Dennison
Phyllis T. Piotrow, PhD

Development Associates, Inc., Arlington, VA
Director, Center for Population Communication,
Johns Hopkins University, Baltimore, MD

95

Nancy Williamson

Judith Helzmer

**Family Health International
Research Triangle Park, NC
IPPF/Western Hemisphere Region
New York, NY**