11. ONGOING RESEARCH PROGRAMME

Titles of ongoing projects:

1. Production of hCG and anti-hCG reagents.
2. Detection of hCG as tumor marker in trophoblastic neoplasms.
3. Study of tumor markers in testicular tumors.
4. Histopathological and immunopathological studies on trophoblastic disease.
5. Teratogenicity of "jamu peluntur" (local herbal abortifacients).
6. Efficacy and safety of local MPA.
7. Comparison of blood lipids levels of women with different contraceptive methods.
8. Blood lipids levels in two kinds of contraceptive users.
9. Blood lipids levels of women with oral contraceptives, IUD: An epidemiological multicentred study.
10. Screening of plants with an antifertility effect.
11. The effect of high voltage electrostatic fields on reproduction in rats.
12. Hormonal profile of normal Indonesian men and women.
13. Cell mediated immune response in infertile males.
14. Return of fertility in DMPA users.

12. MOST IMPORTANT PUBLICATIONS IN FAMILY PLANNING 1982 - 1985:

1. Microsurgical tubal anastomosis: A controlled trial in four Asian Centers. J. A. Rock, Y. S. Chang, K. Limpaphayon, S. Koetsawang, F. Moeloek et al. Microsurgery 5:95 - 95, 1984.
2. 13.000 Voluntary sterilization at Klinik Raden Saleh. F. A. Moeloek et al. Meeting Society of Advancement of Contraception, Jakarta November 26 - 30, Jakarta.
3. The effect of a non-steroidal anti-inflammatory drug on bleeding, menstruation and hemoglobin concentration in IUD users. Andrijono and Lastiko B. In press. (in Indonesian).
4. Knowledge and attitude to abortions among mothers visiting the Utan Kayu MCH Clinic. Hatma Tunggul et al. In press (in Indonesian).
5. Two years experience with norplant implants in Indonesia. B. Affandi & Joedo Prihartono WHO Symposium on Long-Acting agents for fertility regulation, Mexico January 6 - 7, 1984.
6. Delivery system for secure contraception. S. Sumapraja. Indonesian Society for Secure Contraception Congress, Jakarta July 15 - 17, 1984 (in Indonesian).
7. Clinical experience with IUDs. B. Affandi. Seminar on long acting contraception. Jakarta, November 24, 1984.
8. The role of contraceptive safety study in the Indonesian Family Planning Program. B. Affandi. Workshop on Biomedical Research in Family Planning, Jakarta April 14 - 16, 1983.
9. Education and training of medical students in the practice of secure contraception. A. B. Saifuddin & D. Rahardjo. Workshop on the teaching of secure contraception to medical students, Jakarta, October 5 - 7, 1983 (in Indonesian).
10. Gonadotrophin and steroid hormones concentration in women with regular menstruation. I. A. Rachman et al. Indonesian Congress of Obstetrics and Gynecology, Bandung, June 7 - 11, 1982 (in Indonesian).
11. Research on contraceptive research: Complications and referral on Java. Muhyidin, D. et al. Research report 1983 (in Indonesian).
12. Comparative study on low dose oral contraceptives. Bastaman, B. et al. Research report, 1983 (in Indonesian).
13. Acceptance of Norplant in Cengkareng. Bastaman, B. Research report, 1984 (in Indonesian).
14. The effects of poliduri on rat spermatogenesis. Sinto, A. In press (in Indonesian).
15. The effects of testosterone-estradiol implants on sperm motility in rats. Ascobat, F. In press (in Indonesian).
16. The effect of *Carica papaya* seed extract on fertility in male and female mice. Wardhani, H., Suprihatin, S., Tadjudin, M.K. & Soeradi, O. Indonesian Society of Andrology Congress, Jakarta, September 25 - 27, 1985 (in Indonesian).
17. Prolactin concentration in serum and semen of infertile males. Setiorini & Tjokronegoro, A. Indonesian Medical Journal (in press, in Indonesian).
18. Congenital malformations in the offsping of rats after treatment of the testis with electrostatic field. Soeradi, O. & Tadjudin, M. K. Int. J. Androl. (in press).

13. ONGOING TRAINING PROGRAMMES

Formal undergraduate training:

Degrees/diplomas: - Medical doctor

- Science major in reproductive biology

Number of students:

Medicine: 1983: 820
1984: 837
1985: 841

Reproductive biology: 1984: 2
1985: 5

Formal M. Sc. and Doctoral level training:

M. Sc.: - 1984: 3
- 1985: 5

Specialist in obstetrics and gynecology:

- 1983: 42
- 1984: 41
- 1985: 43

Doctor of Medicine (Obstetrics & gynecology): - 1984: 2

Short group-learning activities in 1985:

- Workshop on reproductive endocrinology

In-house staff training programmes:

1. Seminars and symposia in human reproduction.
2. Workshops in research methodology.
3. Workshops in new laboratory methods.

14. FUNDING FROM NATIONAL RESOURCES

Currency: Rupiahs

Rate: 1 US $ = Rp. 1133.-

Salaries:	1984	Rp. 1,733,081,070.-
	1985	Rp. 2,486,229,000.-
Equipment and supplies:	1984	Rp. 47,000,000.-
	1985	Rp. 720,700,000.-

Income from services provided:

- Semen analysis:	Rp. 20,000,000.-
- Genetic services:	Rp. 500,000.-
- Biochemistry:	Rp. 5,000,000.-
- Drug assays:	Rp. 35,000,000.-
- Microbiology:	Rp. 50,000,000.-
- Pathology:	Rp. 35,000,000.-
- Clinical	Rp. 100,000,000.-
- RIA	Rp. 20,000,000.-
- Cytology	Rp. 15,000,000.-

Other sources:

- Research grants:		
University		Rp. 36,300,000.-
Ministry of Education & Culture		Rp. 8,700,000.-
Ministry of Health		Rp. 21,861,500.-
- Donations:		Rp. 50,000,000.-
- Tuition fees:	1983	Rp. 62,320,620.-
	1984	Rp. 68,838,723.-
	1985	Rp. 40,243,549.-
- Operational budget from the government	1983	Rp. 41,440,129.-
	1984	Rp. 39,243,549.-
	1985	Rp. 40,243,549.-

15. INSTITUTIONAL RESEARCH STRENGTHS AND WEAKNESSES

Principal strengths:

1. Commitment of the staff to the success of the National Family Planning Program.
2. Great interest among the staff to human reproduction research.
3. Good links to the BKKBN and other institutes.
4. There is already some manpower trained in research in reproduction.
5. Some basic equipment is already available.
6. Out of all specialists in the field of medicine in Indonesia 40 % works at the School of Medicine University of Indonesia.

Weaknesses:

1. Research facilities are still dispersed among several laboratories.
2. Service of equipment is sometimes difficult to obtain.
3. Reagents and chemicals is also sometimes difficult to obtain.
4. The teaching and service load of the staff is heavy, so that the time which can be spent for research is sometimes limited.
5. Well trained technicians is difficult to obtained, so that most technicians are trained in-service.
6. Research capabilities are still low.
7. Acquisition of equipment is not systematic.

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

HRP/CRR/85
ENGLISH ONLY

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION

THE REPORT OF THE FIRST MEETING OF THE COMMITTEE ON RESOURCES FOR RESEARCH

Geneva, 12-23 August 1985

Contents

1. INTRODUCTION

The first meeting of the newly-formed Committee on Resources for Research (Annex 1) was held in Geneva from 12-23 August 1985. Dr J. Barzelatto, Director of the Special Programme of Research, Development and Research Training in Human Reproduction, in his opening remarks outlined the responsibilities and tasks of the Committee and their relevance to the total mandate of the Special Programme. The Committee, he said, had the dual responsibilities of helping with the efforts being made by developing countries for strengthening their capacities to carry out research and research training related to human reproduction, and of building and maintaining a global institutional network which would collaborate with the Special Programme's task forces in carrying out research in a large number of centres (multi-centre research). In addition he highlighted the need for the Committee to work closely with the task forces and the WHO Regional Offices and emphasized the advantages of collaborating with the efforts being made by other international organizations and through bilateral agreements to strengthen capability for research in human reproduction.

Dr A. Faundes was elected chairman and the Agenda in Annex 2 was followed through in sequence. All policy recommendations were based on preliminary work done first in small groups and followed by a general discussion in plenary.

2. TERMS OF REFERENCE

The Committee on Resources for Research, working within the context of the overall goals of the Special Programme for Research, Development and Research Training in Human Reproduction, will be responsible for the following:

- to plan and recommend strategies for the strengthening of capabilities for research on human reproduction and for the evaluation of such strengthening activities;
- to review proposals for strengthening research capability as these are received, amend the proposals where necessary and recommend priorities where resources are limited;
- to review annually the progress of continuning projects for strengthening research capability, participate in site visits when appropriate and recommend any necessary alterations to planned activities;
- to identify and keep under review institutions or other resources which can assist in the strengthening of research capabilities, including research training;
- to maintain an overview of the network of institutions collaborating with WHO for research on fertility regulation;
- to strengthen and promote collaboration among supported institutions;
- to review, evaluate and follow-up research training activities where these fall outside specific projects for institutional development;
- to promote coordination and collaboration of activities for strengthening capabilities for research into human reproduction by agencies active in the field;
- to make recommendations on any other activities that will enhance the functions stated above;
- to make recommendations on budget allocations for activities stated above.

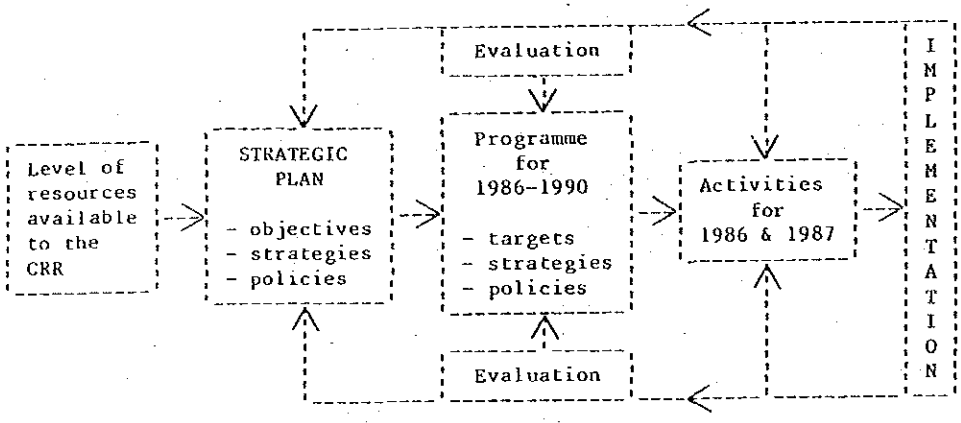
3. A STRATEGIC PLAN FOR THE STRENGTHENING OF NATIONAL RESEARCH CAPABILITIES IN HUMAN REPRODUCTION

3.1 Introduction

A strategic plan is necessary to allocate limited resources to meet a wide variety of needs in strengthening research capabilities in developing countries. The strategic plan outlined here, which was drawn up by the Committee on Resources for Research (CRR) of the Special Programme, for the strengthening of research capabilities related to fertility regulation is not an inflexible set of rules but rather one which provides guidance for the setting of priorities and the allocation of resources.

The plan first describes the context in which the CRR's work will be carried out and then goes on to identify the objectives to be achieved, the strategies to be used for achieving the objectives, and the policies to be applied when CRR resources are being deployed.

The Committee drew up a five-year programme of work for the period 1986 to 1990, based on the strategic plan. It will be initiated with a work plan for 1986 and 1987, which the Secretariat will prepare. The outcome of these two years' activities, as determined by periodic evaluations, may result in changes in the plan in the future. Also, any changes in resources available to the CRR will call for changes in the plan. Thus, this plan is a cyclical one, as depicted in the diagram below.



3.2 The context

The following factors and approaches reflect the CRR's ethos, which has influenced the formulation of the plan.

The present status of research in developing countries into fertility regulation, including infertility

The Special Programme's past efforts have assisted in the establishment of a number of research institutions, mostly in universities in developing countries. Some, particularly in Asia and Latin America, have become strong in research capacities, including the ability to provide training for research. In addition, national research councils or equivalent institutions which promote research in reproduction, in China and India for example, have had their research management strengthened. Many of the institutions which participate in multi-centre trials initiated by task forces have continued to do them well, but only a few have set up independent projects in reproductive biology, development of contraceptives or evaluation of contraceptives. Some institutions, in collaboration with WHO (Division of Family Health, and Regional Offices), have undertaken community studies and other studies related to fertility regulation as part of primary health care.

Relevance to the goals of the Special Programme

Strengthening research capability must be congruent with the goals of the Special Programme. This means that strengthening-activities should both promote the Special Programme's research priorities and strengthen national and regional research capacities.

Institution-strengthening programmes based on dialogue with institutions

An active dialogue between the Special Programme, national authorities, and the research institution, should be the basis of efforts to strengthen institutions. Needs, objectives and processes should be defined by national authorities rather than by the Special Programme.

Research of national relevance

The Special Programme's resources for strengthening institutions should be used to promote research of national relevance, while at the same time an institution's resources may be used for the research needs of task forces. Such research will inevitably involve linkages of research institutions to national family-planning programmes and a broadening of the research to include not only biomedical research but also social-science approaches to research into the provision of services.

Collaboration with task forces

While there is a growing emphasis on strengthening research capabilities to meet national and regional needs, the training potential of multi-centre trials should not be underestimated, particularly in countries where basic data-collection skills are weak. Moreover, these trials have brought to light problems that call for research specific to these countries. Participation in task force multi-centre trials should serve the purpose of enabling countries to plan, coordinate and carry out research, analyse data, and disseminate research results. Task forces can help to strengthen institutions in several ways. They can see that scientists in supported institutions take part in the planning and development of task force research agenda and protocols, and they can collaborate with the CRR in its training strategies; this would include the provision of technical assistance at training workshops, and consultant site-visits to CRR-supported institutions.

Collaboration with WHO Regional Offices and other agencies

Communication and collaboration among agencies engaged in strengthening research capabilities are needed to make the best use of scarce resources and to avoid duplication. This should apply not only at agency headquarters but also regionally and locally. Collaboration should attempt to include multilateral and bilateral governmental mechanisms as well as private organizations.

Regional networks

The WHO Regional Offices should reinforce inter-institutional collaboration initiated at regional levels, by means of training support and technical assistance. These should not come solely from WHO Headquarters. Those institutions that have achieved a higher degree of self-reliance in research should serve as centres for training and sources for consultation for the less developed programmes and institutions in the regions.

A scientific approach to the solution of problems related to fertility regulation in developing countries

The development of research capability should emphasize a rational approach to prevalent problems in fertility regulation. Good research does not require sophisticated technology, and good research ideas are not limited to those institutions that have sophisticated technical capabilities.

The importance of management in institutional development

Institutional development is heavily dependent on the local availability of managerial competence both at the national policy level and in the institutions. Promoting managerial competence in the supported institutions is of high priority to the CRR.

Special Programme funds for institutional development

The report of the Preparatory Intersessional Committee (PIC) forecasts the availability of funds for institution-strengthening as follows:

> "In 1980, 41.7% of HRP's resources were devoted to institution strengthening but this has now fallen and is due to remain constant at about 30% through to 1987."

The adequacy of this proportion can only be judged on the future pace of growth of institution-strengthening activities. In addition, the United Nations Fund for Population Activities (UNFPA) has provided US$2.2 million in 1985 for the first year of a five-year cycle of progressively diminishing support, specifically to strengthen institutions in China and Indonesia under programmes formulated with the governments of these countries. Acting in WHO's role of Executing Agency of these projects, the CRR is kept informed of the progress of the projects and helps in monitoring them to ensure high scientific standards. On the basis of its assessment of progress, the CRR can recommend changes in the planned programme, to be discussed with UNFPA and the national authorities.

The basic values established by the World Health Assembly

The World Health Assembly has repeatedly stressed the importance of assisting developing countries in their efforts to achieve self-reliance in health research. They need to be self-reliant to solve national health problems; to cooperate as active partners with other countries for the solution of indigenous health problems; and to participate in the expanding global scientific enterprise. These values will pervade the work of the CRR.

3.3 Objectives

The CRR's mission is to promote a global network of research and training programmes related to fertility regulation. Such research activities are possible only if there are competent research workers in well-equipped and well-managed research institutions in all countries concerned about fertility regulation. WHO's Seventh General Programme of Work specifies a target for these activities:

> "By 1989 this programme will have strengthened to the point of self-reliance research facilities in developing countries that have national policies on and services for family planning".

The strengthening of an institution occurs primarily by means of the efforts of its managers and researchers. The CRR's role can only be to promote and support what are essentially national and institutional efforts. Nevertheless, with a broad vision of the goal of a global network of nationally supported institutions engaged in high-quality research and training in all aspects of human reproduction, the CRR proposes to focus on the achievement of the following objectives, at institutional, national and regional levels:.

In institutions

- a 'critical mass' of researchers competent in the basic biological, pharmacological, clinical, epidemiological, biostatistical and social sciences, performing quality research of national relevance and of scientific importance;
- scientific leadership and managerial competence in all supported institutions;
- educationally sound programmes of training for research related to fertility regulation;
- strong linkages with national family-planning programmes;
- strong national support for the institution's research and training activities, as demonstrated by the creation of suitable research career structures and by progressive increase in the national funding of research into fertility regulation;
- well-maintained physical and laboratory facilities for the investigations required for research into fertility regulation and for the processing of data;

- a research review mechanism to assess productivity and to evaluate and disseminate research results;

- a mechanism for the regular review of progress in training programmes and in total institutional development;

- a mechanism for peer review of proposed research and to ensure ethical standards;

In each country

- an efficient system or organization for the national coordination of research into fertility regulation, to ensure that research is not unnecessarily duplicated; that research and evaluation results are translated into practice; that local resources are efficiently coordinated; and that the research corresponds with the national definition of research needs and priorities;

- a close collaboration between the family health service systems and the research institutions;

- increasing national support for research and research training related to all aspects of fertility regulation;

- a national forum for the research workers where they can present and discuss their results with programme personnel, policy-makers and administrators.

In each region

The regions referred to here are broad geographic regions, and not necessarily the WHO regions. In the regions, research strategies must take into account the political constraints that make collaborative programmes difficult, but provide for the maximum exchange of experience and information within and between the regions. The CRR will aim at achieving the following goals:

- collaborative research programmes between neighbouring countries with similar problems, especially problems concerning access to fertility regulation services;

- 'centres of special expertise' that play a regional role especially for research training in the academic disciplines, including the social sciences, required for research in human reproduction.

- active collaboration in institutional development among institutions engaged in Special Programme-supported programmes of institution-strengthening.

The CRR is willing to support national and local research, particularly in those countries whose governments have committed themselves to assume phased responsibility for supporting the research. However, it must be recognized that not all governments do so. Some that do not yet recognize the need for research policies or family-planning services may do so once research findings demonstrate the need. Such countries should not be categorically excluded from efforts to strengthen research capability, nor should those countries which may have the interest but lack the economic resources to absorb support for research institutions. Support should go to the kind of research that a country is likely to support in the long term.

3.4 Strategies

When drawing up broad strategies for the strengthening of research capacities, the CRR recognized that there are, in developing countries, institutions that may fall into any one of the three phases of development that are described below:

(a) In countries where there is no continuing research concerned with fertility regulation, universities should be recognized as focal points for efforts to develop institutions. However, the strengthening of research capabilities should not be restricted to universities, especially in countries that lack strong academic research traditions. CRR in such instances should identify promising individuals with potential for

scientific leadership, wherever they may be, and support the development of research capability around them. In such circumstances the support will be mainly for staff development with a view to creating a 'critical mass' of research workers. Wherever possible, the more developed institutions in the Special Programme network will be given the opportunity of training these individuals.

(b) In countries where research in fertility regulation has recently begun, either at universities or at other institutions, the first step would normally be to identify the most suitable institution, in consultation with the national government. Such institutions will usually need a mixture of support for the training of their staff and for instrumentation, as well as a substantial amount of consultant advice on-site to assist in the preparation of good research protocols.

(c) In institutions which the Special Programme has been supporting for more than about 10 years, and where research is well established, strengthening activities will consist mainly of assisting scientists to apply for funds for research projects from task forces or other agencies. Here, the CRR will have to consider requests for some support for staff training, mainly to learn specific new investigative techniques and to keep in touch generally with advances in the field. In addition, some small support will be needed for the supply of laboratory instruments. However, the main concern of the CRR will be to assist some of these institutions to train scientists from less-developed institutions, and to maintain them as active units of the Special Programme's network. Also, they may need a single capital grant to pay for the replacement of major items of equipment. Such grants may also help a well-developed institution engaged in another area of health research to divert its interests to research in fertility regulation. When providing funds for a major piece of equipment, it should be recognized that the cost of purchasing the equipment is only a fraction of the total cost involved: adequate support for maintenance, operations, supplies, spare parts and training should be provided for when an application for a capital grant is being prepared.

In all these phases in the development of an institution, CRR resources will be needed to promote continually sound research management. Institutional changes resulting from such support should improve not only institutional management but also internal communication, priority setting and accountability.

The CRR's resources should also be used to improve the linkages of the institution being strengthened to national family-planning programmes, relevant policy forming and administrative bodies and to institutions outside the country.

Besides strengthening new institutions the CRR will be expending some resources in promoting the creation of centres of special expertise in the developing countries, in selected areas such as epidemiology and the social sciences.

Many developing countries are now creating formal national mechanisms for the regulation of drugs, including contraceptives. The CRR would collaborate with such efforts technically and consider proposals for the strengthening of such mechanisms as part of long-term institutional development plans.

3.5 Policies

In supporting an institution's long-term development the CRR will give priority to countries where national authorities have agreed to assume gradually the costs of recurrent local salaries and expenditures provided initially by the CRR. National development plans may include provision for such take-over if the CRR discusses the matter with national governments and obtains their agreement before it begins to strengthen institutions.

Long-term support to institutions should be given on the understanding that they would train research workers for less developed institutions.

Research training of individuals will be funded only in the context of explicit long-term plans for the development of staff of institutions in developing countries. Trainees should be assured in advance of a post on their return, in which they could carry out research. Whenever possible, all or part of the research undertaken as part of research

training for a Ph.D. should be carried out in the research worker's own institution or country.

Institutions being supported should either be the research arms of national family planning programmes or have established active links with such programmes.

The research carried out under support for institution strengthening or for research training should have protocols stating the hypotheses to be tested and have good research designs as judged by peer review. Also the protocols must be subject to ethical review. However, while it is recognized that protocols, well-formulated hypotheses, and carefully defined research designs are essential, many institutions in the early phases of development may lack the skills to meet these requirements. In such cases technical assistance and training will not only help to develop a fundable project, but also in itself serve to strengthen research capacity.

Support for research training programmes (Ph.D. and Master-level courses and short courses) should as far as possible be provided to institutions in developing countries where there are continuing research activities related to fertility regulation. Proposals for such support should incorporate in their objectives training in preparing research protocols. The curriculum plans, and plans for programme evaluation and follow-up, should be included in the proposals.

The individual character of each institution should be recognized when decisions are made on support. Not every institution will fit easily within the general strategies and policies outlined above.

While it is important that the process and outcome of all support be regularly monitored, care should be taken to avoid burdensome and too frequent external evaluations.

When an institution receives support from the Special Programme, a clear distinction should be made between funds for strengthening research capacity and those for carrying out a research task initiated by a task force, even though the task force support also has a strengthening effect.

Long-term continuous support to institution-strengthening should be the minimum required to achieve self-reliance and in any case should not exceed 10 years. However, after such support, the institution may continue to receive funds for task force work and in addition may apply to the CRR for small amounts of funds for research training, laboratory supplies and journals.

4. PROGRAMME FOR 1986 TO 1990

4.1 Introduction

In the programme outlined below, the CRR assumes that the resources available for strengthening institutions will remain fairly constant over the next five years and that the programme will be consistent with the strategic plan. In 1984 the Committee on Institution Strengthening, now replaced by the CRR, provided funds in the form of 'core support' to the institutions listed under section 17. This 'core support' consisted of a mix of funds for meeting expenses of task force multi-centre trials and of institution-strengthening. The latter component usually included provision for the purchase of major equipment and journals.

Some of the current group of institutions have received a constant stable level of 'institution strengthening support' since the inception of the Special Programme in 1972. Others began to receive support during the past 10 years, and, in a few cases, in Africa, support began only two or three years ago. In the past, judgements of progress in institutional development were made to a large extent on the basis of how well an institution performed with respect to task force multi-centre trials. This latter was an important element in the criteria for designating an institution a WHO Collaborating Centre. Recommendations for such designations, and for de-designations, were made by the Committee for Institution Strengthening and reviewed by the Special Programme's Advisory Group.

4.2 Targets

During the next five-year period the following targets should be reached:

(a) Institutions which have been supported for more than 10 years: These institutions will no longer receive long-term support from the CRR. In many cases CRR support can end by the end of 1986; their support is already entirely task force related, and they receive funds also from other agencies that support research in human reproduction. Some will need a two-year phase-out period; several are receiving fees for the training of researchers from less developed institutions.

(b) Institutions which have been supported for less than 10 years: These institutions will have undertaken a well-planned programme of institutional development, including staff development, will be carrying out research of relevance to their national fertility-regulation programmes, and also collaborating with the task forces.

(c) New institutions: Several 'new' institutions, especially in countries with national fertility-regulation policies but no major national research support, will have formulated realistic development plans and be receiving CRR support in the form of institutional grants and training grants.

(d) Increase in research careers: There will be a significant increase in opportunities for research careers in the developing countries, especially as the institutions take over salary support provided initially by the Special Programme.

(e) More M.Sc. programmes: Master's degree programmes in the field-oriented sciences (epidemiology and the social sciences), for the training of researchers will have started in the developing countries and be used for the training of Special Programme-supported trainees.

(f) Improved regional collaboration: There will be increasing regional collaboration amongst institutions in fertility-regulation research and research training.

(g) More inter-agency collaboration: There will be increasing collaboration among agencies with programmes for strengthening institutions. Well-developed formal channels of communication between such agencies will be maintained at all administrative levels. WHO Programme Coordinators will play key roles in developing and maintaining communication at national levels.

(h) Improved research management: There will be significant improvement in research managerial practices in all CRR-supported institutions.

4.3 Strategies, policies and justification of targets

In order to add support to new institutions, support to the strengthening of already established institutions must decline. This decrease in support will be planned carefully with the recipient institutions so as to assure maximum self-reliance. Therefore, as a pre-condition to receiving further support, institutions that have been supported for five years or more must submit plans for phasing it out. These plans should be based on the recognition that there will be variations in the level of institutional development and in the time needed to achieve self-reliance. In some cases the funds may be phased out over two years while in others the period may be longer. Details of phase-out plans will be agreed between the institution and the Special Programme and included in each institution's five-year plan.

The CRR, in supporting the development of centres of special expertise in various disciplines related to research into fertility regulation, will maintain geographic balance.

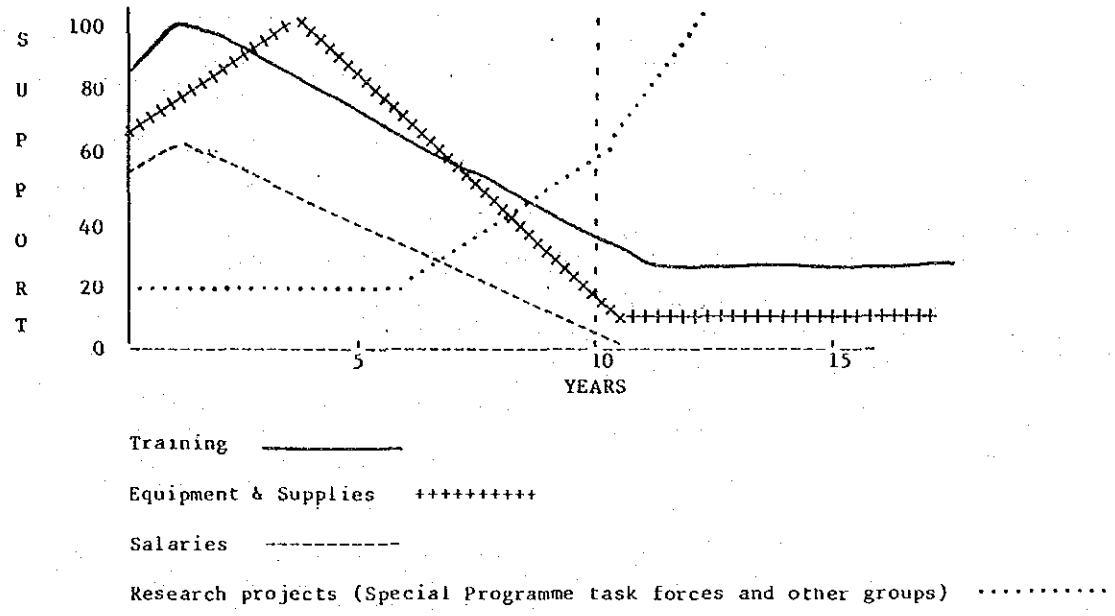
As funds for strengthening institutions are phased out, it will happen that, because technology is changing rapidly and equipment has worn out, some institutions may need one-time capital grants to replace or upgrade equipment.

Some countries have established Master's-level programmes in the social sciences, but training in epidemiology is generally lacking and will be recognized as a priority for development.

At least four workshops (one each for institutions in Africa, Asia, China and Latin America) will be held over the five-year period for the training in research management of directors of institutions undertaking research into fertility regulation, and directors of national family-planning programmes and persons responsible for national research policy.

All institutions applying for support for the training of their staff in research will be requested to submit institutional profiles and plans for staff development. The latter should identify the broad lines of the research they propose to carry out.

The normal course of the various types of Special Programme support to institutions is envisaged as in the following diagram:



Support to institutions will be by means of a system of institutional grants and training grants. The application forms for grants will provide for the inclusion of five-year plans for institutional development. The CRR will carry out an annual review of progress and of continuation of funding. It will prepare an information booklet which will outline main policies and give details of grants and of grant application procedures. Applications for grants to institutions should identify institutional research lines in fertility regulation. The planning, designing and conduct of research projects by institutional staff will be one of the main means of strengthening institutional capacities.

5. DESIGNATION OF COLLABORATING CENTRES

The issue confronting the CRR was whether it should continue, as in the past, to be responsible for recommending the designation of institutions as WHO Collaborating Centres for Research on Human Reproduction. It noted that several WHO programmes make extensive use of the practice of designating Collaborating Centres, and that others use it rarely, if ever. Programmes such as the Special Programme, with a large commitment to research, undertake or encourage research in collaborating institutions, whether designated or not, and thus underscore the concept of collaboration between WHO and specific institutions.

The importance which institutions assign to WHO designation varies from country to country. In some it seems of only minor importance whereas in others it assumes greater significance. The advantages of WHO designation to an institution or a department are largely those of prestige and credibility in the eyes of government and of the national family-planning programme. Also, designation as a WHO Collaborating Centre may help in attracting funds for research from other agencies, national and international.

The CRR noted that designation indicated formal recognition that institutions meeting certain specific criteria were collaborating with WHO. It recognized also that there are several institutions collaborating with WHO for research into human reproduction which have not been so designated.

After discussion on whether designation as a WHO Collaborating Centre was a component of institution strengthening, the CRR decided that it was not. Accordingly the CRR recommended that it should not be directly responsible for making a decision to designate or to terminate designation of institutions collaborating with WHO. At the same time it noted that when reviewing the progress of institutions that have received support for strengthening research capability it may recommend those institutions that fulfil the WHO criteria for designation to the Director of the Special Programme for consideration for designation.

6. RESEARCH TRAINING GRANTS

6.1 General issues

Five-year plans of institutions

All institutions should initiate and formulate five-year plans for research development, including staff development, giving details for the first year.

The institutions should formulate their plans preferably in consultation with Secretariat, consultants and concerned national authorities. The plans should reflect country priorities in reproduction research.

Flexibility is necessary to modify plans as an institution develops, but the objectives, research plans, staff development (training, courses, etc.), consultant visits, resources, equipment and budget should be identified at the start to facilitate a comprehensive development plan. All concerned must recognise that plans are subject to budgetary changes.

The overriding considerations in planning training programmes are the quality of the training and its suitability within the context of the five-year plan. Once these are agreed there are a number of options and types of training that can be applied according to the institution's needs. These may range from long-term training completely away from the institution, through training partly at home and partly abroad, through short-term technical training, to in-house training in the home institution

Length of training

Length of training should be tailored to the needs of institutions, with a balance of short (up to one year) and long (up to three years) periods. Countries with low research capability will need long-term training to develop a "critical mass" of research workers. It may often be desirable to train several workers, not necessarily at the same time, from one institution to achieve this "critical mass". Short-term training provides technical expertise, but longer training, to Ph.D. level, is necessary for all-round research capability.

Normally, a research trainee should receive substantive instruction from one institution, avoiding the confusion that might result from exposure to variations introduced by short periods spent at several.

The time required for trainees to overcome cultural changes, and in particular language barriers, should be recognized in determining the length of training.

In principle, trainees should be away from the home institution for the shortest possible time commensurate with attaining the required skills.

Location of training

Trainees should be sent to the institutions that can best meet their training needs. There are many options, according to the state of development of the institutions concerned.

These include full training for long periods (e.g. Ph.D.) at a foreign centre; registration at a foreign university with the work period spread abroad and at home to retain local interest and relevance in the trainee's research; registration at the home university with training abroad for an appropriate period; short visits abroad to acquire particular technical skills; or full training at home.

Where possible, external supervisors should visit the home institution to help supervise the trainee and to promote closer inter-institutional collaboration in the longer term. Formal "twinning" of developed and developing institutions may not be necessary, but informal arrangements along these lines may encourage inter-institutional team-work and commitment.

The CRR should make every effort to identify institutions in developing countries that can provide training, thereby fostering technical cooperation amongst developing countries (TCDC). For this purpose the institutional directories prepared by the WHO Regional Offices should be consulted.

Development of initiative

Returned trainees, and institutions as a whole, should develop their own research programmes, consistent with institutional and national priorities. Task force designed protocols are important but institutions should not be required to depend entirely upon them, as they limit local initiative and self-reliance.

6.2 Distribution of Research Training Grants

The distribution of grants by region, country and discipline must be determined largely according to country requests and stage of development. The CRR should recommend a general policy related to regional and country priorities, and to regional imbalance. The numbers to be trained according to discipline should follow from institutional five-year plans. Broader country and regional needs should also be considered.

In the past, the emphasis has been on training related to the development of contraceptives. It should now include training in health-services research, epidemiology, statistical analysis, clinical research and demography. However, essential basic-science training in fertility control methods should not be overlooked.

Trainees should understand that their training is for their institutions and countries and that they should return from training to contribute to the institution's research and training activities.

6.3 Award of Research Training Grants

The CRR considered that the present arrangements for the award and administration of these grants were adequate and well carried out.

Each trainee's special needs should be discussed with the training centre, as close supervision and support are often necessary. The supervisor should outline in writing the plan of work, and the trainee's institution should be in agreement with it.

Close contact between the home institution and the training centre should be fostered throughout the period of training and beyond to encourage continuity of interest. Communication should include regular reports of the trainee's progress.

Institutions engaged in task force research, even if they are not receiving Special Programme institution-strengthening support, should be eligible for Research Training Grants. While applications from institutions being strengthened should receive priority, excellent applications from individuals from other institutions should not be ignored.

6.4 Follow-up on return of trainees

Most trainees return to their home institutions or to other institutions collaborating with WHO. Annual reports from institutions should describe the progress of returned trainees in some detail. Applications for re-entry research grants should be prepared in consultation between the home institution and the training supervisor. Where appropriate, the supervisor

should visit the former trainee 6-12 months after the end of training. Close liaison should be fostered between supervisors at home and abroad.

Trainees who can function as independent research workers should be eligible for re-entry research grants, whether or not they come from institutions receiving strengthening support.

6.5 Training plans

An integrated, multidisciplinary approach to training should be part of an institution's development plan. All institutions receiving support should prepare these plans, including the long-established institutions, where the trend to independence, self-reliance and home country support should be evident.

Training grants should be focused on building up a "critical mass" of scientists in specific institutions rather than spreading individual research workers over too broad a base. However, excellent individuals in other institutions who may be well qualified to work with national programmes or task forces should not be excluded.

6.6 Evaluation

At suitable intervals (perhaps five years) the training programme should be evaluated in depth. Evaluation should encompass both the training programme and the progress of trainees. The evaluation should include consideration of papers published and the performance of trainees in their institutions.

7. STRENGTHENING RESEARCH TRAINING FACILITIES (M.Sc. Courses)

7.1 Adaptation of existing courses

Where a course is essential, it should be based in an institution with sufficient infrastructure, staff and resources to carry out the training. If possible, it should be an adaptation of an existing course, with modifications or additions requested by the Special Programme, rather than creation of a completely new course.

7.2 New courses

M.Sc. courses (of 1-2 years) are expensive to develop anew. They require an adequate administrative basis, sufficient staff and provision for curriculum development and examinations. The Special Programme should consider such courses only when other means of training are not available.

At the same time, postgraduate education is a priority in many developing countries. A case can be made for M.Sc. courses - in epidemiology and social science related to reproduction, for example - when there are too many potential trainees to send to established courses in developed countries. Such courses may be seen as part of an institution's development and the Special Programme can help with advice and initial assistance.

7.3 Location of courses

If the above conditions can be met, institutions in developing countries should be selected in preference to others.

7.4 Requirements for courses

An assessment of the needs of M.Sc courses should be presented at the next CRR meeting. This should specify the topics, why the training cannot be obtained elsewhere, an analysis of the resources and infrastructure of the proposed host institution, and the number of trainees estimated. Without such information, the CRR found it difficult to address the issue further at this meeting.

8. SUPPORT FOR SHORT GROUP-LEARNING ACTIVITIES (WORKSHOPS, SHORT COURSES, SYMPOSIA)

Short group-learning activities on specific topics have proved to be valuable for promoting research in human reproduction. They are cost-effective, especially when located in institutions collaborating with the Special Programme. They have been used in a workshop format where the participants, using the expertise available in the group, have produced research protocols for implementation on return to their home institutions. Short courses, such as the andrology courses and RIA courses, have been used for the transmission of knowledge and for learning laboratory techniques. Symposia have brought together experts in a field for presentation and discussion in front of wide audiences. The following policies should apply to CRR support of short group-learning activities.

- They should be well-planned and be an integral component of an institution's research development programme.

- Great emphasis should be placed both on experiential learning of practical items and on discussions in small groups. Formal lectures should be kept to a minimum. As far as possible, the curriculum should relate to the participants' research and, where appropriate, culminate in the production or revision of participant research protocols.

- Planning should occur in close consultation with the host institution whose staff should be utilized as far as possible in teaching and follow-up of participants. The preparation and use of learning modules should be explored.

- Participants should be carefully selected vis-a-vis their research potential and performance and in consultation with the Special Programme. The number of participants should be limited, especially for the practical courses, but may be larger for those of the didactic type. In some instances participant attendance may be made cost-effective if held in conjunction with large international meetings.

- Applications for support should be made in a structured format which will be developed by the Secretariat. Either task forces or institutions may initiate the applications.

- In addition to responding to requests, the CRR should have its own plan for courses to meet the overall requirements of research development. The plan should include courses in health-services research, research methodology and research management. Health-services research is a good focal point where researchers and health care providers could meet to foster mutual understanding of each other's roles. However, the planning and implementation of short group-learning activities in health-services research can be difficult, since it is a young science and has only recently been institutionalized in university settings.

- Evaluation should form an integral part for the purpose of future improvement of such activities. Such evaluation should include both student and teacher perceptions of the process and outcomes. Follow-up of the research performance of the participants is essential and should be the responsibility of the host institution and the Special Programme.

9. INSTITUTIONAL GRANTS

A new system of institutional grants will be introduced, for which institutions in developing countries can apply. These grants, together with training grants, will be the main mechanisms by which an institution's capacities for research into fertility regulation will be strengthened and maintained.

The following types of institutional grants, to meet the varying needs to research institutions, will be developed:

Long-term institutional development grants
Capital grants
Small grants
Grants for small supplies

9.1 Institutional grants

Long-term institutional development grants

Institutions that have not previously received substantial strengthening support from the Special Programme, and other "new" institutions in developing countries, will be eligible to apply. The application forms for these grants will call for the following five categories of information:

(a) Institutional profile: Baseline data on the institution, as indicated in section 16 (Institutional Evaluation);

(b) Five-year plan: A five-year plan for developing the institution. This plan will contain the following information:

- proposed research lines to be developed in fertility regulation and in research to determine needs for fertility regulation programmes;
- research training activities to be developed in the institution;
- the institution's programme for its staff development;
- linkages to be developed with other national and foreign institutions.

(c) First-year plan: A detailed plan for the first of the five years. This should include:

- research lines to be followed and detailed research protocols for specific projects to be carried out within each research line;
- training programmes to be conducted in the institution during the second year;
- staff development activities;
- linkages to be developed and maintained.

(d) Five year support and budget: Request for support and approximate budget for each of the five years, in the following categories:

- Salaries: These salaries will be for new staff and will be in accordance with national salary scales. The amounts requested for each year should reflect progressive national takeover of salaries. However, the total amount requested from the Special Programme may increase if the number of staff increases annually.
- Consultant support: approximate costs of consultant support to be provided for each of the five years.
- Training grants: These need not be costed.
- Equipment and supplies: The costs will reflect a progressive national assumption of responsibility for the costs of equipment and supplies, although the local cost may increase.
- Data-processing facilities
- Library resources
- Vehicles and transport

(Other items to be included in the form will be specified by the Secretariat.)

(e) First-year support and budget: Detailed request for support for the first year for each of the categories listed in the five-year plan and should include separate budgets for each of the research protocols.

Capital grants

This is a single large grant meant for a fairly well-developed institution to enable it to acquire a major piece of equipment, either to replace an old one or to divert institutional research interests towards research into fertility regulation. It will be useful specifically for institutions that have had Special Programme support for a long period but find themselves in need of replacing a major piece of equipment acquired during the period of Special Programme support. The application form for these grants will call for information requested under sections 2. and 3. of "Long-term support grants" and for a budget.

The budget for such grants and for all major equipment to be provided under a long-term support grant will include costs of spare parts and maintenance, indicating the source of funding for operation and maintenance.

Small grants

These are mainly for institutions that have completed their period of Special Programme support, to enable them to acquire small supplies and journals. The Secretariat will draw up a form for such grants. It was agreed that this grant would not exceed US$5,000 but the CRR wishes to review this figure later.

Grants for small supplies

See Chapter 16.

9.2 Mechanisms for dealing with specific research protocols requested under long-term support grants

The proposals for long-term support grants are expected to arrive in Geneva in June 1986 and to be seen by the CRR in July 1986. Specific research protocols should be reviewed only after CRR approves in principle the application for a grant for long-term support. The purpose of the CRR review will be to attempt to improve the protocols rather than to approve them or turn them down. Hence a review mechanism for the research protocols will be instituted during or after the CRR meeting in August 1986.

9.3 Grants for institutions that have had ten years of institution-strengthening support

After they become "centres of special expertise", some of these institutions will be used as training centres for Special Programme-supported trainees . To perform this function they will be eligible to apply for the following types of support:

(a) Capital grants
(b) Small grants
(c) Tuition fees for Special Programme-supported trainees
(d) Research Training Grants and Visiting Scientist Grants
(e) Designation as Collaborating Centres
(f) Assistance with hormonal assays-reagents, quality control, etc.

Institutions in developed countries will be eligible to apply only for (c), (d) - for specific task force needs only, (e) and (f).

9.4 Summary of CRR grants

Institutional grants:

		Approving body
- Long-term support		CRR
- Capital	CRR	
- Small		TRC*
- Small supplies	TRC*	

Training Grants:

- Research Training	TRC*
- Visiting Scientist	TRC*
- Master's degree courses	CRR
- Short group-learning (workshops, seminars, etc.) exercises	TRC/CRR
Re-entry research (after technical and ethical review)	TRC*

10. IMPROVING INSTITUTIONAL RESEARCH MANAGEMENT

10.1 Introduction

For the purposes of the CRR, it was felt to be useful to consider research management at two levels:

(a) The macro management level, of the research institution;
(b) The micro management level, of individual research projects.

It was agreed that managerial competence in both of these areas is lacking in many developing countries, and that the Special Programme should try to provide assistance to institutions in developing countries to improve research management skills of their managers and scientists.

10.2 Management of institutions

The objectives in managing a research institution should be to develop, coordinate and facilitate research activities, as well as to disseminate research results. The institution could be a department, a single institution, or a network of institutions. The approach to strengthening the mangement of research institutions will vary according to the type, size and complexity of the institutions. The research management needs of small departments concerned primarily with teaching and service provision should be considered in the larger context of that department's activities.

The director and senior managerial staff of a research institution should have a strong grasp of the nature and conduct of research. They should if possible be experienced researchers, with a genuine interest in management issues.

Institution-management includes:

- Strategic planning, including the setting of goals, objectives and priorities;

- Staff development, including the formation of research teams as well as the career development of individuals;

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* Technical Review Committee (TRC). This is a committee consisting of members of the Secretariat, which meets about once a month.

- Dissemination of information, both internally and externally;
- Administration of physical plant, equipment and supplies;
- Coordination of all institutional activities;
- Development of a management information system;
- Financial management;
- Periodic supervision and evaluation of research activities and productivity.

To overcome deficiencies in institution management skills, the following strategies are recommended:

(a) Directors of large research institutions should make provision in their institutional plans for the delegation of certain managerial responsibilities. For example, managers of institutions could be charged with the administration of physical plant, maintenance of equipment and financial management. Operations officers could assist with the technical aspects of research management.

(b) Senior management staff should take advantage, where available, of local courses of training for management offered by private and public organizations. Inventories should be compiled of such resources. Medical research councils should also be considered as institutions which could provide training in the management of research institutions.

(c) Selected management staff at larger institutions should be offered specialized training in business administration.

(d) Regional seminars should be organized, when indicated, for senior management staff. The purposes of topics for such seminars would include the management activities listed in 9.2.3 above. Individuals representing other national institutions that have important links with research institutions should be invited to attend such workshops. They could include representatives of the academic unit in which the research institution is located, of the national medical research council, and of agencies that provide service.

(e) The services of management consultants should be retained when indicated for larger institutions on a medium-term (three to six months) basis to provide assistance in improving management practices.

(f) Institution management manuals should be prepared and made available to managers, particularly with regard to financial administration.

(g) Inter-agency collaboration in management development should be encouraged, to avoid unnecessary duplication of effort.

(h) The Special Programme should assist institution managers to set up management information systems. At larger institutions, this could consist of a highly structured computerized data base. At smaller institutions, one individual could be assigned the task of setting up and maintaining an institutional data base.

10.3 Management of Research Projects

A research project is managed to ensure that it progresses on schedule and in accordance with the research protocol, that it results in accurate and complete collection, analysis and reporting of data, and that it is accomplished entirely within the allocated budget.

The managers of a research project are the project leader or principal investigator and the associate investigators. Although different levels of staff have various management functions, the principal investigator has overall responsibility for the project.

Management of a research project includes:

- drawing up the research proposal and preparing the application for funding, including the requisite national clearances;
- the planning and ordering of project activities;
- adequate documentation of all project activities;
- for clinical trials, organization of clinic activities, including follow-up procedures for subjects ensuring the maintenance of good ethical standards;
- Allocation of staff, equipment and supplies;
- Allocation of funds and monitoring of expenditures.

To overcome deficiencies in the management of research project, the CCR made the following recommendations:

(a) Formal research training programmes should include the subject of research project management as an integral component;

(b) Prospective principal investigators should obtain first-hand experience in managing research projects by functioning as associate investigators on projects;

(c) Workshops and short courses on mangement of research projects should be organized when needed for investigators. Objectives would include the management activities listed in 9.3.3 above.

(d) Both (b) and (c) above should be included in an institution's staff-development plan.

(e) Research management manuals should be prepared and made available to investigators.

It should be emphasized that lines of communication between investigators and managers of institutions and national authorities should always be clear and open.

In summary, the Special Programme and other agencies should actively promote skilled management as a component of institutional development. Any proposal for strengthening research capability must include provision for the development of appropriate management skills at all levels of staff.

11. STRENGTHENING BIOSTATISTICAL, EPIDEMIOLOGICAL AND DATA PROCESSING CAPABILITIES

11.1 *Introduction*

In previous years the main emphasis on institution strengthening has been on the provision of training and facilities in reproductive biology, laboratory techniques and other biomedical sciences. Many of the collaborating institutions have thereby built up or upgraded their research facilities, and staff have gained much experience in the conduct of high-quality research in human reproduction. However, since a substantial number of these research projects were multi-centre in nature, they were designed and statistically analysed with outside assistance, especially from Geneva, and the collaborating institutions have not made comparable gains in acquiring expertise in this area. To be more effective and self-sufficient in their research, scientists in the collaborating institutions should have ready access to biostatistical and epidemiological advice as well as data-processing facilities. Basic biostatistical skills are an essential part of a researcher's training. Strengthening capabilities and facilities in these areas assures that each institution can design its own studies, and collect, manage and analyse statistically the resulting data.

The strategy for strengthening resources will depend on such factors as the amount of research undertaken, the level of development of the institution, and the facilities already present in the institution or in sister institutions located at a convenient distance. The basic plan may need to be modified to fit the needs of individual institutions, depending,

for example, on the existence or strength of links with another department such as a university department of community medicine or statistics. Institutions should explore, establish and use such links to their fullest extent before seeking to strengthen their own capability. If there are no such departments or links, the department itself would have to be strengthened, and the institution would be required to assume, in due course, financial responsibility for the posts.

11.2 Targets

The requirements for managing and analysing clinical and epidemiological research data may be viewed at three distinct levels - institutional, national, and inter-country.

Institutional

Each institution, for which the justification exists, should aim to be self-reliant as regards the statistical, epidemiological and data-processing needs of its research workers. The staff should be able to design, manage and analyse the results of research projects. To achieve this a nucleus of trained statisticians, epidemiologists and computer scientists needs to be established, and the corresponding computer hardware and software provided. This group should be able to conduct its own research and develop methodology for the specific problems of family-planning research.

Clearly, the requirements of individual institutions differ, but nonetheless the eventual aim should be the establishment of at least a minimum facility. For an institution conducting a limited amount of research this minimum might consist of:

(a) one staff member with a Master's degree in biostatistics with a large component of statistical computing;

(b) one data-management/data-entry assistant trained locally;

(c) a large microcomputer with basic programming facilities, and statistical and data management packages.

An institution conducting a limited amount of clinical trials and epidemiological work would need a larger staff and premises - at least:

(a) one staff member with a Master's degree in biostatistics and epidemiology;

(b) one staff member with a Masters degree in computer science;

(c) two data management/data entry assistants trained locally;

(d) similar computer hardware and software as above, but with additional storage space.

Estimated costs of plans

All inclusive costs for the above plans will vary with the place of training. Estimates provided below are for the United States of America. Costs are slightly lower in the United Kingdom.

Approximate costs for an institution of the first type, with no current facilities, are:

Two-year overseas training	US$50,000	
Computer hardware and software	US$20,000	
Spare parts for computer	US$ 2,000	
TOTAL		US$72,000

For the larger type of institution costs are estimated as:

Two year overseas training for two staff members	US$100,000	
Computer hardware and software	US$ 25,000	
Spare parts for computer	US$ 2,500	
TOTAL		US$127,500

Estimates should include, as far as possible, the costs of servicing and maintaining computer equipment. However, the institution should eventually absorb these costs.

National

In addition to the institutional requirements, each country in which research is being conducted in family planning should be able to meet the biostatistical, epidemiological and computing needs of its national research and population programmes. Country-specific multi-centre clinical trials addressing problems of national concern should be planned, coordinated and analysed at a national focal point. The focal point should function as a training and support centre for the needs of other institutions in the country.

Inter-country

In any given region, an institution could develop so as to be able to support other institutions, e.g. by training and technical assistance. Where appropriate, such support should foster technical cooperation amongst them.

11.3 Strategy

Biostatistics, epidemiology and data processing should be strengthened within the framework of the CRR's strategic plan and each institution's plan for research development. Priority should go to institutions that already have some capacity in these fields so that they may in time serve as resource centres.

Specific proposals for institutions should provide for the coordination of institutional activities with similar activities of other programmes of WHO and other agencies. The CRR specifically suggests that the Special Programme takes the initiative for an inter-agency consultation in the near future to coordinate efforts at institution-strengthening in this area.

11.4 Selection of training programmes

Institutions and programmes for the initial training of biostatisticians, epidemiologists and computer scientists should be selected in accordance with the general guidelines for research training, which seek to ensure that such training is suitable for both the home institution and the country. Further training of such specialists may best be carried out in direct conjunction with the work of the Special Programme at the global, inter-country or country level.

12. NON HUMAN PRIMATE RESOURCES FOR RESEARCH IN HUMAN REPRODUCTION

12.1 Background

The last five years have seen a marked drop in the availability of non-human primates for biomedical research. The increasing scarcity of animals from the wild, due to destruction of their native habitats and the encroachment of human populations, has been accentuated by bans on exports of primates (e.g. rhesus monkeys, marmosets) imposed by several source countries. The problem of availability of primates will certainly become even more acute over the next five years.

At a time when stocks of primates for research are dwindling, there are increasing needs of non-human primates for research on fertility regulation and for development of new methods of regulating fertility.

It is recognized that no primate species is completely similar to the human as regards reproductive physiology, biological/biochemical indices, or hormonal profiles/metabolism of hormones. It is therefore more efficient and cost-effective to use a range of primate models that will satisfy the varied needs of research into human reproduction.

In the past the rhesus monkey has been the mainstay of the biomedical research worker. With its increasing scarcity alternative models are needed (e.g. the baboon, which shows no seasonality in male or female; the bonnet, of which the male has no seasonality; the

marmoset, which breeds rapidly in captivity; the Cebus, the only New World species which menstruates; and the vervet).

12.2 Recommendation of the Advisory Group to the Special Programme

The Advisory Group at its meeting in October 1978 "considered that primate models for research in reproduction were urgently needed. The programme was encouraged to develop primate centres, with quality control and standardization, in general, and to meet the needs of several Task Forces".

In pursuance of the recommendations of the Advisory Group, the Special Programme of Research in Human Reproduction has supported a few centres in source countries (namely Argentina, India, Kenya, Pakistan, Thailand) for development of their primate facilities.

12.3 Requirement of non-human primates for research in human reproduction

A survey of current use and estimated annual requirement of non-human primates by task forces shows considerable increase in the next two years (Table 1). These needs will continue to increase rapidly over the next few years as more preparations and devices resulting from research supported by the Special Programme reach the stage of development that requires evaluation of efficacy and safety in primates.

It would be most appropriate for the Special Programme to strengthen the primate facilities in the source countries and use them for its research needs, for the following reasons:

(a) The primate facilities fulfil the Special Programme's objectives in supporting the development of the facilities which:

- maintain the animals under accepted husbandry conditions;
- have well trained scientists to carry out research supported by WHO task force and conduct other studies specific to the interests of the centres;
- provide in future adequate numbers of non-human primates to meet the needs not only of specific task force studies but also of evaluation of the efficacy of new antifertility agents developed by the Special Programme.

(b) studies in the source countries would be much less expensive than those conducted elsewhere;

(c) adequate numbers of animals are still available and can be used for studies, as and when needed;

(d) scientists from non-source countries can carry out collaborative studies on adequate numbers of animals;

(e) the primate facilities could train scientists from other developing countries; this would conform to the spirit of technical cooperation among developing countries and also would make the trainees aware of the problems which developing countries face in setting up similar facilities.

12.4 Advantages to the Special Programme of availability of primate facilities in source countries

- Permit the best use to be made of the expertise, facilities and resources of the source countries including Old and New World species;
- make available in source countries (a) non-human primates of standardized quality, and (b) expertise for pre-clinical evaluation of fertility-regulating agents;
- enable the Special Programme to provide leadership in the promotion of the judicious use of non-human primate in research in human reproduction in source countries, without endangering natural primate resources;

TABLE 1: TOTAL REQUIREMENTS OF NON-HUMAN PRIMATES FOR ALL TASK FORCES (approximate)

NHP	1985		1986		1987		REMARKS
	Male	Female	Male	Female	Male	Female	
BABOON	8	152	8	172	?	?	
RHESUS	20	20	25	40	25	?	
BONNET	40	25	40	90	40	90	
CYNOMOLGUS	15	20	15		15		
	80	80	80	80	80	80	Toxicology
MARMOSET	30	50	50	70	20	20	

- permit the improvement, standardization and quality control of research methodology in use of non-human primates for research in reproduction;

- enable scientists, with adequate numbers of primates of good quality, to initiate and conduct collaborative studies in source countries. Such studies would not only be cost-effective but also foster international collaboration;

- permit the evaluation of fertility regulating agents and other studies. These studies would be cost-effective and could be carried out on larger numbers of animals.

12.5 Conclusions and Recommendations

Previous support

The Special Programme has supported a number of primate centres in the past. These continue to be available to the Special Programme. The centres in developing countries include those in Bangkok (cynomolgus), New Delhi (rhesus), Nairobi (baboons, vervets) and Buenos Aires (Cebus, marmosets).

Current support

Two centres, those of New Delhi and Nairobi,continue to receive funding. Both receive institution-strengthening and task force support. In addition, a centre at Bangalore, India receives support from the Male and Post-ovulatory Task Forces.

Scientific development

Background knowledge of the reproductive physiology of the species held in these centres is now available. Much more specific questions may now be asked, and will need to be asked in the following task-force areas if the new methods of fertility regulation being developed by the task forces are to be pursued to best advantage:

(a) Long-acting agents
(b) Post-ovulatory methods
(c) Plants
(d) Male
(e) Toxicology

It should be noted that primates are necessary in these areas because rodents are not adequate animal analogues (with regard to gamete development, implantation, and corpus luteum function). In addition, most drug regulatory agencies have legal requirements for the testing of new agents in primates.

Primates may be seen in many cases as developing-country resources, providing a dimension of scientific endeavour that can provide a distinctive character to research in these source countries at a fraction of the cost of similar research in developed countries.

Future Support

Research that makes use of primates is essentially long-term and expensive. When task forces need non-human primates they may find it necessary to provide adequate notice and funds to the centres, to ensure that the primates will be available when they need them. Otherwise, other national and international programmes that need primates for research purposes may be competing with them for these scarce resources.

It may be advisable to designate a few centres in developing and developed countries as the Special Programme Collaborating Centres for Research in order to retain their commitment. This need not be linked to funding.

Guidelines for Special Programme involvement

(a) The Special Programme should consider seriously the establishment of new primate facilities, as centres have already been developed for current task force needs. An exception could be made if a particular species is a unique model for a particular question that cannot be answered with current facilities.

The Special Programme should provide expertise and advice, based on its considerable experience, if countries request resources to develop primate research.

(b) Support for institutional strengthening should be given only to centres in developing countries.

(c) Where possible, primate facilities should be associated with current Special Programme research centres (as in Bangkok, New Delhi, Nairobi).

13. STRENGTHENING OF CLINICAL AND EPIDEMIOLOGICAL RESEARCH

13.1 Introduction

One mandate of the Special Programme is to promote research into the safety, efficacy and acceptability of methods of fertility regulation. However, many developing countries lack the capacity to undertake clinical and epidemiological research. Many are establishing their own drug regulatory agencies. To make an informed judgement as regards the approval of any new method of fertility regulation, the agencies must be able to carry out well-designed and well-conducted clinical trials within the country. Institutional strengthening should have as its final goal that countries interested in conducting clinical and epidemiological research in fertility regulation should have the capacity to do so. The extent to which this goal can be achieved in the next five years will depend on the availability of funds.

Strengthening the capacity for clinical and epidemiological research should be seen as part of an institution's development plan. Access to epidemiological expertise should be reflected in an institution's profile, and, if needed, should be part of the plan for staff development.

13.2 Recommendations

Strengthening of clinical research capacity should be based on actual clinical research. Learning could be undertaken in relation to task-force multi-centre studies, nationally or regionally originated collaborative studies, or single-centre studies. No multi-centre trials should be suggested to an institution unless everyone engaged in the research understands the study or will be helped to understand it. All investigators should take part in preparing the protocol. All documents and research instruments should be made available in the local working language.

Training should have three components:

(a) Before the start of the study, a short course or workshop can be held for the whole research team to discuss the research protocol.

(b) Training during the research trials by means of meetings of the regional investigators when the final protocol is being prepared, a few months after the subjects are enrolled, and when the computed results are being analyzed.

(c) The assignment of consultants to accompany all the processes of the study, from conducting the initial course or workshop, participating in the investigators' meetings, and visits to provide supervision and training at intervals during the trials.

The number of qualified epidemiologists in developing countries who have an interest in research in human reproduction should be increased. Since epidemiology courses usually do not refer to research into fertility regulation, a short course is recommended, after training in epidemiology, which would demonstrate its applications to fertility research.

Short courses in epidemiology should also be provided for scientists conducting research into fertility regulation. However, these scientists should have access to a well-qualified epidemiologist for advice and consultation.

The Special Programme should provide support requested, within the institutional-strengthening process, for clinical and epidemiological research that may be only indirectly related to fertility regulation (e.g., maternal mortality). This may create

the capacity for clinical and epidemiological research in fertility regulation. The results of such research may also demonstrate the need for research and services in fertility regulation.

There should be consultations on this issue with other WHO programmes with related interests.

When the CRR is developing facilities for clinical and epidemiological research, ministries of health should be involved.

There should be inter-agency collaboration in the organization of workshops and training courses in clinical and epidemiological research e.g., in the assignment of consultants to conduct workshops, and in the funding of research protocols that are drawn up in workshops.

14. STRENGTHENING OF RESEARCH IN SOCIAL SCIENCES

14.1 Introduction

The Committee identified a need in developing countries to strengthen research capabilities in social sciences in the areas related to fertility regulation. This need occurs at local levels because fertility behaviour is socially and culturally determined, as well as being influenced by factors associated with provision of services. Three specific problem areas can be defined:

(a) In many developing countries a cadre of trained social scientists already exists but often they lack interest or expertise in research related to fertility and are not linked to family planning programmes.

(b) Biomedical and clinical research workers generally lack knowledge of social-science methodologies and often fail to understand the importance of including social-science approaches in their research.

(c) Communication and collaboration between biomedical and social scientists is often weak or altogether lacking.

14.2 Long-range goal

Within its goal of strengthening institutions and developing resources for research, the Special Programme should, in every country where institutions are being, or to be, strengthened, promote the development of capability for research into the behavioural and social determinants of fertility regulation.

14.3 Objectives

(a) Priority must be given to fostering communication and collaboration between social and biomedical scientists in research.

(b) Social scientists must be made aware of the importance of, and opportunities for, research in the area of human reproduction and must become involved in such research.

(c) Biomedical scientists and institutions must become more aware of the special skills of social scientists and of applications of social-science methods in research on fertility regulation.

14.4 Strategies

To enhance communication and collaboration between social and biomedical scientists:

(a) The Special Programme, especially through its task forces, should promote and support collaborative projects;

(b) Linkages should be sought at the country level, for example between a national family-planning board and social-science institutions; and at the institutional level, for example between departments of obstetrics and gynaecology and departments of community medicine, which often include social scientists on their staff.

(c) The Special Programme should make it known that funds are available for interdisciplinary research projects originating at the local or country level.

To increase awareness and interest of social scientists in fertility research:

(a) Incorporate courses in fertility determinants into established social-science training curricula;

(b) At the level of large institutions or national programmes, provide long-term training for carefully selected individuals in programmes that combine social science and fertility research, and assure career structures for them within institutions once they are trained. Such long-term training should be targeted at social scientists with an interest in fertility research.

(c) Inter-country training centres should be established, preferably where there is an established interest in research into fertility regulation within a social-science training programme.

To increase awareness on the part of biomedical and clinical researchers:

(a) The Special Programme should make known to biomedical research workers its interest in social science research.

(b) Short courses can provide an orientation to social sciences and help establish communication with social scientists.

(c) Invite biomedical and clinical research workers to seminars and meetings where social science research in fertility is discussed and presented.

The general guidelines in the CRR strategic plan should apply to this area, as to others, particularly:

(a) Depending upon the size and type of institution, long-term plans for institutional development should include plans for communication and collaboration between biomedical and social scientists;

(b) The Task Force on Behavioural and Social Determinants of Fertility Regulation should play a key role in institutional strengthening in this area;

(c) In developing or strengthening centres that can serve as regional resources for training and consultation, priority should be given to institutions where there is an expressed interest and established base of skilled individuals; such institutional strengthening should not occur in isolation from family-planning research and service programmes;

(d) Inter-agency coordination should be stressed to avoid duplication and to actively promote interdisciplinary collaboration in funding projects;

(e) In addition to inter-agency coordination, there should be efforts to coordinate in this area with other WHO programmes.

Specifically, the CRR should:

(a) provide long-term training for carefully selected individuals to increase the number of social science researchers working in human reproduction;

(b) award long-term institutional-strengthening grants to develop inter-country training centres. In awarding these grants, priority should be given to expanding centres that have already been receiving Special Programme support;

3. organize short courses for both biomedical and social scientists to orient them to the useful applications of social sciences to research in fertility regulation;

4. make funding available, either through the Task Force or the CRR, to support research for those individuals who have already been sponsored by the Special Programme for training in social-science research;

5. transmit this report to the Steering Committee of the Task Force on Behavioural and Social Determinants of Fertility Regulation to reinforce the coordination and collaboration needed between the CRR and the task force if social science research is to be incorporated into the human reproduction research programme.

15. PROGRAMME OF STANDARDIZATION AND QUALITY CONTROL OF LABORATORY PROCEDURES

15.1 Introduction

The Programme for the Provision of Matched Assay Reagents (MRP) was set up in 1976/77 together with an associated External Quality Assessment (EQA) Programme. Standardization programmes were established for clinical chemistry and haematological parameters as well as (in collaboration with the National Institutes of Health, USA) a reagent programme for the measurement of gonadotrophins in non-human primates. EQA schemes for steroid glucuronides in urine and synthetic steroids used in contraception have also been set up.

The main objective of the programme is the standardization and quality control of laboratory procedures. This is implemented by the provision of immunoassay reagents and supporting services (training, education in internal quality control, external quality assessment, and technical advice) to centres assaying reproductive hormones in accordance with the objectives of the Special Programme. These include assays carried out in connexion with specific projects of Special Programme task forces and also, in some centres, as part of institution strengthening for research.

Secondary, but integral, objectives are the development and evaluation of new methodology for possible application to research in fertility regulation, and the encouragement, by means of training and providing reagents, of local and regional independence in hormone assay for research in this area.

During the last two years the programme has encouraged the formation of national reagent programmes and is setting up an international bank of key reagents for immunoassay. The programme supplied 65 laboratories in 31 countries with approximately 2500 sets of assay reagents for each hormone. It is hoped that national agencies will supply immunoassay reagents in the future, and train staff in laboratory procedures. The ultimate role of the WHO programme is envisaged as being coordination between national and regional programmes, and acting as a resource for supply and interchange of key reagents through its reagent bank. The programme would also evaluate new methodologies, some of which would have been developed by national schemes, and help in adapting them for research in reproductive physiology as well as for general use in developing countries.

These activities have saved the Special Programme approximately $14 million since 1976 and have contributed to its objectives, as the availability of well-established analytical procedures allows many centres to conduct research on the endocrinology of human reproduction, particularly the effect of fertility-regulating agents, and to monitor the treatment of infertility. They are consistent with the principles of technology transfer and enhancement of research and health-care capabilities of institutions in less developed countries.

In summary, the programme:

(a) provides matched reagents to centres engaged in research into human reproduction;

(b) provides an external quality-control service;

(c) maintains a bank of key reagents;

(d) promotes the development of national programmes for the supply of assay reagents;

(e) supports research for developing and improving hormonal assay techniques.

To facilitate these activities the Special Programme supports a Collaborating Centre at the Chelsea Hospital in London, UK.

After review of the information provided, the following observations and recommendations were made:

15.2 Matched-reagent programme

The matched-assay-reagents programme (MRP) has been a success and has contributed in a significant way to the standardization of laboratory results not only from CRR-supported laboratories but also from others outside the network. It was noted that owing to the supplies provided to the laboratories outside the network the MRP was running satisfactorily, and that in 1984 and 1985 the programme received US$154,503 and US$131,595, respectively. The budget of $560,000 for 1986, recommended by the Steering Committee, was endorsed.

15.3 The Collaborating Centre at Chelsea

The Collaborating Centre remains an essential resource for research activities under the Special Programme, and will continue to play this role for the foreseeable future.

The Centre's services should be maintained at the same level and, in addition, its resources should be called upon in the development of national or regional programmes.

It would be appropriate for the Centre to undertake the development of new methods, particularly non-isotopic assays economical and suitable for use in developing countries. The priorities in this regard should be determined in conjunction with the Steering Committee on the Programme on Standardization and Quality Control of Laboratory Procedures and the task forces.

More collaboration should take place between task forces and the Centre.

The requested budget for the centre was approved including, the capital and running costs for the bank of reagents.

15.4 Bank of reagents

The Committee approved the setting up of an international bank of key reagents for immunoassay (including non-isotopic) methods. The cost of setting it up - US$235,000 in 1986 and an annual recurrent budget of US$60,000 was approved.

15.5 Internal quality control

The Committee did not approve the funding of an internal quality-control programme based at Chelsea because it felt that each laboratory in the WHO network should be capable of establishing its own control system.

15.6 National programmes

The Committee endorsed the setting up of national or regional programmes in India and Cuba or Mexico. It recommended that the resources at Chelsea should be utilized for this purpose; this would be one reason for establishing a bank of reagents at Chelsea to provide standardization of national or regional matched reagents.

When these national programmes are established they will take up role of supplies to other national centres.

In setting up the national and regional programmes the CRR's general guidelines for institutional strengthening should be applied.

The following budgets were approved:-

India:	$86,000 plus Research Training Grants
Cuba/Mexico:	$41,000 plus Research Training Grants

15.7 Development of new assay techniques

It was noted that in the proposal from the Stockholm Collaborating Centre funds had been requested for the development of non-isotopic methods, particularly chemiluminescence and time-resolved fluorescence. The budget requested was approved under the grant to Stockholm.

16. AD HOC PROVISION OF SMALL LABORATORY SUPPLIES AND JOURNALS

16.1 Supplies

The small-supplies programme is a valuable source of support for reproductive research, particularly in the developing countries. The CRR made the following recommendations after having reviewed the background of this scheme and listened to first-hand experiences.

The continuation and expansion of this scheme should be permitted within the overall budgetary constraints of the proposed five-year CRR plan.

It will apply only to centres which are not currently receiving and have not received, institutional strengthening support. Immediate attention should be paid to improving geographical spread of this type of support.

The programme should be directed at developing countries and those with hard-currency constraints.

The amount of support for each centre should be limited to US$1,500 annually.

Eligibility should be assessed by a simple grant scheme with a minimum of bureaucracy. A one-page application form should be developed by the Secretariat.

The Secretariat should establish detailed criteria for a successful application; in general, they should include:

(a) the laboratory should be engaged in research of quality and relevance in the area of human reproduction;

(b) the institution must give valid reasons for the grant;

(c) the supplies requested are not available for purchase in the country.

The scheme should be advertised, especially through the Regional Offices.

The scheme should be part of the CRR five-year plan. The programme should be monitored and a review carried out before the end of that period.

16.2 Journal subscriptions

Journals should be supplied under the approved budget for institutions receiving support.

It was agreed that those institutions that are being phased out should become self-supporting as to journal subscriptions.

The Special Programme should help those with inadequate library support by providing suitable annotated bibliographies.

It is recommended:

(a) That the provision of journal subscriptions to institutions other than those receiving long-term institutional strengthening should cease as of 31 December 1986 and that, meantime, the Special Programme should develop alternative mechanisms for facilitating access to information about human reproduction research for such centres.

(b) There should be discussions between the Secretariat, the library staff at WHO and the Regional Offices as to the best procedures to be followed in achieving this. Suggestions might include direct access to "MEDLINE" services or distribution of computerized annotated bibliographies. In this context repository libraries and use of focal libraries may be explored.

(c) The Secretariat should explore the possibility of commercially available annotated bibliographies.

17. GUIDELINES FOR THE EVALUATION OF INSTITUTIONAL DEVELOPMENT

Previous evaluation practices of the Special Programme were discussed; it was noted that these may have had more to do with the goals of the Special Programme's research than with self-reliance. However, it was agreed that site visits, which formed part of the evaluation process, were, themselves, a highly effective way of assisting institutions. The new strategic plan for institutional development calls for a more structured means of assessing progress from a defined base-line to defined goals.

Evaluation of institutional development is a critical component of any strategic plan for the strengthening of research capability as it provides a basis for changes of strategy when activities are failing to meet objectives, or reinforcement of strategies when milestones are being reached on time. Evaluation should be based on an assessment of changes in structure and functioning of the institution and its impact on local and national programmes.

Evaluation should not be confused with monitoring, which is concerned with ensuring that planned activities are completed on time. Evaluation is much more concerned with the outcome and impact of these activities. Monitoring should be the role of the institution and the Secretariat. Continuous monitoring is vital to the institution strengthening process and should be carried out by the institution itself as part of day-to-day management practices as well as by the Secretariat through site visits. Both evaluation and monitoring should be conducted in the spirit of cooperation and assistance.

For evaluation to have meaning there has to be a clear set of objectives and a baseline against which successive assessments can be judged. Thus at the start, and for each institution, there needs to be a profile of the institution's resources. The profile should describe, preferably within a standardized format, the characteristics of the institution against which change can be judged over a period of several years. Such a profile also might include descriptive material which probably would not be used in a regular evaluation but which would help to place the institution within a national, regional or global context.

It is suggested that each institutional profile should include descriptions of a number of characteristics, clearly showing strengths and weaknesses. The following preliminary list requires further elaboration.

- policies and objectives;
- research programmes and their sources of support;
- training programmes and their sources of support;
- organizational structure;
- research and research management staff;

- physical resources for research;
- access to human subjects;
- access to library resources and other support services such as statistics and equipment maintenance services;
- scientific and ethical review mechanisms;
- funding from other sources;
- national commitment to the institution;
- publications of staff (number, citations and quality);
- links with other departments or institutions for research, research training, and research services;
- linkages with the national family-planning programme or comparable programmes;
- training programmes for research;
- commitment to the institution by the "mother" institution;
- other specialized training;
- role and impact of the institution within and outside the country concerning research into human reproduction.

Evaluation of institutional development should be both by the institution's internal mechanism and by external evaluation.

The ability to undertake critical self-assessment is itself a sign of institutional maturity. From the beginning of the strengthening activities, institutions should be encouraged to assess these activities internally and document this assessment. One way in which internal assessment can be done is by the preparation of annual reports on the basis of the variables in the institutional profile. These reports should thus act as a stimulus for internal discussions on progress, identification of problems, and future plans.

External evaluation serves a number of purposes. It permits the Special Programme, and ultimately the Special Programme's donors, to chart the progress of activities for strengthening research capability. Fed back to government it provides that body with an independent view of a national institution. Fed back to the institution it gives an objective appraisal against which future plans can be laid. External evaluation should also be based on the characteristics which go to make up the institution's profile. Overall external assessment should be carried out by the CRR with active participation of national authorities, on the basis of both annual reports and reports of site-visits.

Site-visits should be carried out for three overlapping purposes:

(a) monitoring of project activities;
(b) technical monitoring and assistance; and
(c) evaluation.

The first two of these are largely the responsibility of the national authorities and WHO Secretariat and should be carried out annually, as a general rule; some institutions may need more frequent visits.

To fulfil the second purpose, site-visits will sometimes require the addition of one or more technical consultants. The inclusion of such consultants in these site visits will promote scientific exchange which is so important for institutional development. A certain degree of continuity is needed in regard to such consultants, either using the same person or using persons from the same institution; consultants from other institutions being strengthened by the Special Programme should be used whenever appropriate. Finally, it would improve the quality of the evaluation to include members of the CRR in a consultant capacity from time to time on such visits.

As regards the third purpose of site-visits, evaluation, it is recommended that visits for this purpose take place approximately every three years and that national authorities, independent consultants, and those who carry out regular monitoring activities should take part. The composition of such teams should be carefully thought out and appropriately balanced, and the members should be made aware beforehand of specific problem areas which require special attention.

In addition, it is suggested that, two to three years after institutional strengthening has been phased out, an independent evaluation of its impact be carried out.

The CRR, on the basis of annual reports and site visit reports, will thus be able to assess the progress of institutional strengthening towards agreed objectives and be able to recommend appropriate modifications in these objectives and the activities, inputs, work-plans and budgets which would be required to achieve them.

18. BUDGET

The budget lines on page 34 were recommended for operations (in US$1000).

19. FUNDS RECOMMENDED FOR 'CORE SUPPORT' TO INSTITUTIONS FOR 1986

The funds approved for each of the institutions are given on page 35.

20. DATES OF FUTURE MEETINGS

The next meeting of the CRR will be from 25 July to 2 August 1986.

In 1987 two meetings are proposed:

- 6-14 March 1987
- 24 July - 1 August 1987

	1984 Actual	1985 Estimated Obligations	1984-85	1986-1987 Proposed Budget			1988-1989 Projection		
				Continuing[4]	New[5]	Total	Continuing	New	Total
Institutional grants[1]	724	625	1349	2200	1050	3250	2200	1200	3400
Training grants[2]	813	1100	1913	2000	1300	3300	2000	1450	3450
Network support[3]	108	110	218	200	-	200	250	-	250
Sub-Total	1645	1835	3480	4400	2350	6750	4450	2650	7100
Standards & Quality Control	460	500	960	1114	355	1469	1110	80	1190

1. Includes, from 1986, long-term support grants, capital grants, small grants, and small supplies.

2. Research training grants, visiting scientist grants, re-entry grants, short group-learning activities.

3. In 1984-85 funding referred to small supplies and journals, and from 1986 it includes costs of regional meetings of scientists and research managers.

4. Continuing: budget at present levels of Special Programme funding.

5. New: additional funds based on needs in developing countries that can be used if the Special Programme's total income is increased to the level of the Proposed Programme Budget.

19. FUNDING SUMMARY (in US$)

Institute	Year designsted/ Year support commenced	CIS recommendation in 1984 for work in 1985	Funds for Task Force work in 1986	Funds for institution strengthening (excluding training) in 1986	Total approved at First CRR meeting
Alexandria	1972	33,753	28,056	5,756	33,812
Bangkok Chula	1976	168,256	80,055	22,115	102,170
Bangkok Siriraj	1972	45,205	42,999	2,078	45,077
Bombay	1972	1,337	-	5,000	5,000
Cali	1980	42,829	41,000	829	41,829
Chandigarh	1972	76,572	69,500	5,623	75,123
Cotonou	1981	17,000	-	15,000	15,000
Dakar	1983	2,000	-	15,000	15,000
Hangzhou	1984	189,000	50,000	71,465	121,465
Havana	1976	74,890	43,000	36,850	79,850
Santiago de Cuba	1983	18,539	8,000	3,380	11,380
Hanoi	1979	13,387	8,000	2,293	10,293
Ibadan	1972	2,000	-	-	-
Karachi	1976	35,911	-	2,600	2,600
Leningrad	1977	22,200	20,000	768	20,768*
Ljubljana	1972	52,428	33,650	700	34,350
London	1980	47,902	-	-	-
Lusaka	1975	35,000	32,500	34,526	67,026
Manila	1972	34,500	33,170	1,370	34,540
Mexico	1972	114,373	96,933	22,342	119,275
Moscow AURCMCC	1972	35,000	24,741	10,259	35,000
Moscow IEEMC	1972	15,000	11,670	3,330	15,000
Tashkent	1981	15,000	14,000	1,000	15,000
Yerevan	1981	15,000	14,000	1,000	15,000
Nairobi (ObGyn)	1984/1979	110,400	85,000	22,355	107,355
Nairobi (RBU)	1984/1979	60,000	-	45,100	45,100
Nairobi (IPR)	1974/1979	104,250	46,750	11,000	57,750
Nanjing	1981	165,615	17,527	51,140	68,667
New Delhi	1972	116,373	68,125	9,423	77,548
New Delhi ICMR	1980	2,300	-	-	-
Panama	1984	3,000	-	-	-
Salvador	1972	38,318	37,000	1,207	38,207
Santiago	1981	86,713	80,417	1,819	82,236
Seoul	1972	38,856	20,000	972	20,972
Shanghai**	1979	369,500	19,954	65,535	85,489
Singapore	1972	304,220	283,000	28,187	311,187
Stockholm**	1972	496,000	400,462	14,000	414,462
Szeged	1972	56,898	46,024	2,567	48,591
Tunis	1978	43,481	35,000	15,000	50,000
Wuhan	1981	159,053	49,300	55,171	104,471
Yaoundé	1983	76,707	-	23,000	23,000
SUB-TOTAL		3,339,766	1,839,833	609,760	2,449,593
Ankara	1978	43,000	36,000	-	36,000
London (Chelsea)	1978	120,000	120,000	-	120,000
Shanghai	1979	-	31,321	-	31,321
Stockholm	1972	-	94,538	-	94,538
TOTAL - HRP		3,502,766	2,121,692		2,731,452
Beijing	1980	417,500	-	-	811,000
Chengdu	1982	482,000	-	-	255,500
Guangzhou	1985	373,000	-	-	425,500
Tianjin	1982	440,500	-	-	270,000
Indonesia	1983	156,000	-	-	412,000
Kuala Lumpur	1985	349,159	-	-	120,482
TOTAL - UNFPA		2,218,159			2,294,482

* Leningrad: Proposal not received prior to meeting, however funding level suggested by Secretariat
** See below for additional Task Force funding
Confidential assessments made by CRR of each institution are available from Secretariat

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION

COMMITTEE ON RESOURCES FOR RESEARCH
Geneva, 12-23 August 1985
Salle A

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WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

SPECIAL PROGRAMME OF RESEARCH, DEVELOPMENT AND RESEARCH TRAINING IN HUMAN REPRODUCTION

First meeting of the
Committee on Resources for Research (CRR)
12-23 August 1985

ANNOTATED DRAFT AGENDA

1. Opening of the meeting

2. Introductions; work arrangements; adoption of agenda

3. Setting the stage for the work of the CRR

A background paper has been sent in advance. This gives an overview of HRP's past work and achievements related to research capability strengthening, mainly for the purpose of orienting members to future directions of work. Following a brief presentation by the Secretariat, the participants may clarify any specific aspects in the background document.

4. CRR's Terms of Reference

A background paper has been sent in advance. The CRR needs to clearly specify its own mandate for submission to the Scientific and Technical Advisory Group (STAG) and the Policy Coordination and Advisory Committee (PCAC). The outcome of the deliberations will be a statement of CRR's broad responsibilities and tasks. The general criteria for future membership of the CRR could also be specified.

5. General plans for future work:

5.1 A global strategic plan for strengthening national research capacities in human reproduction

Using the Secretariat background document as a guide, a strategic plan for strengthening research capabilities in human reproduction needs to be formulated. This plan, which should identify the important aspects of institution building, will determine the basic approaches to be adopted in HRP's research capability strengthening activities.

This plan will take into consideration the very important aspect of HRP's collaboration with other agencies involved in institution strengthening.

5.2 Work programme for 1986 to 1990

Having decided on the essential strategies and based on them a broad programme of work for the next five years should be developed.

July 1985

5.3 Specific activities to be implemented in 1986 and 1987

For the guidance of the Secretariat the activities to be implemented over the next two years will be specified. Since some of these activities are dependent on the outcomes of agenda item 20, it would be logical to take-up this item towards the end of the meeting.

6. Policies regarding the designation of Collaborating Centres

HRP's recommendations with respect to designating, redesignating and dedesignating Collaborating Centres has on occasions run into problems. It was within the mandate of the Committee on Institution Strengthening (the predecessor of the present CRR), to make such recommendations. This whole issue needs examination within the context of the WHO regulations on Collaborating Centres. A background paper has been sent in advance.

7. Research Training, Visiting Scientists and Re-entry Grants:

7.1 Review of active grants

7.2 Policies for the award, administration and evaluation of grants

These grants are awarded to enable scientists and supporting staff, mainly from developing countries, to learn new knowledge and technologies in another institution, usually in a developed country. Secretariat will present data on grants and policies for consideration by the CRR. Based on this information, the CRR, if necessary, may wish to recommend any policy changes.

8. Strengthening of research training facilities:

8.1 Review of past activities

8.2 Policies for the future

M.Sc., other postgraduate level programmes and institutional resources for the training of researchers on topics related to human reproduction need to be further developed. This particularly applies to epidemiological aspects and the social sciences. There will be a review of past activities. Policies for future CRR support need to be developed.

9. Support for short group-learning activities (i.e. workshops, seminars, etc):

9.1 Review of past activities

9.2 Policies for the future

HRP supports many activities of 1-3 weeks duration for training and for exchange of information. Some of them result in the formulation of research protocols while others do not. Initiatives for such activities arise both in the institutions and in HRP. A review will be made of these activities and their implications for institution strengthening will be considered.

10. Grants for strengthening institutional resources:

10.1 Long-term institutional grants

10.2 Capital grants

10.3 Small grants

At present HRP has no formal grants for institution strengthening, for which institutions or national authorities could apply. It is proposed to have three types of institutional grants. The long-term grant will be on a gradually declining scale over a 5 to 10 year period (?), during which period the institution or national government assumes greater responsibility for the recurrent funding. Capital grants and small grants will usually be a single input into an institution which is fairly well established or is about to embark on an institution strengthening exercise. The conceptual basis and the procedures to be adopted for the award and the administration of these grants will be discussed.

11. Improving institutional research management practices:

11.1 Review of past activities

11.2 Proposals for the future

The concept of institutional research management refers to two types of activities in institutions:

(a) administration of the institution, including the coordination of national and institutional research;

(b) designing, managing and monitoring individual projects.

Information gathered during the recent site visits indicate that both these aspects are weak in many developing country institutions. The prevailing situation needs to be reviewed and appropriate strategies developed to improve the situation.

12. Strengthening of biostatistical facilities:

12.1 Review of past activities

12.2 Programme for the future

Information has been obtained from Collaborating Centres on the present resources they have for the processing and analysis of data. This information will be reviewed and future activities for improving and expanding these facilities will be discussed.

13. Strengthening of non-human primate facilities:

13.1 Review of the present situation

13.2 Dicussions on future policy

Data obtained from a recent survey of non-human primate facilities will be presented. A decision should be made on CRR priorities for the further strengthening of such facilities.

14. Strengthening of clinical and epidemiological research

The strengthening of clinical and epidemiological research in developing countries has occurred mainly through participating in multicentre trials. Clinical and epidemiological research is of high priority for developing countries. Decisions should be taken on how to promote such research.

15. Strengthening of research in the social sciences

The Task Force on Behavioural and Social Determinants of Fertility Regulation has discussed this issue in-depth. Its deliberations will be presented for discussion. CRR should decide on appropriate activities that would synergise this endeavour.

16. Strengthening of hormonal and biochemical assay facilities:

16.1 Review of past activities

16.2 Programme for the future

Hormonal and biochemical assay facilities in developing countries are still not optimal. HRP has initiated training programmes for scientists and supporting staff and has also supplied some of the equipment required for such work. The present situation will be reviewed by Secretariat and CRR needs to decide on future activities.

17. Programme of Standardization and Quality Control:

17.1 Annual report

17.2 Review of the Chelsea Collaborating Centre

17.3 Approval of budgets

A brief review will be made of this programme, which is advised by a separate Steering Committee, for the purpose of approving the budgets proposed.

18. Ad hoc provision of small laboratory supplies and journals:

18.1 Review of activities

18.2 Future policies

HRP has been providing small laboratory supplies and journals to a large number of institutions on an ad hoc basis. The CRR needs to decide whether this form of institutional support will continue in its present form or whether changes need be made. In this context, the issue of support for equipment maintenance will also be considered.

19. Guidelines for the evaluation of institutional development

For the CRR to know whether a supported institution is growing it needs to have "objective" data on the institution's performance. This data should then be compared against standards or criteria in order to make a judgement of worthiness (i.e. an evaluation). Guidelines need to be developed both for the collection of data and for establishing standards.

20. Review of individual proposals

In the light of the policy decisions which will be made on agenda items 5 to 18, each institution that is currently receiving support will be reviewed in-depth by two CRR members. The review will be based on the institutional director's own report of activities for the previous year and on the site-visit reports. The institution's proposal for support during 1986 will be considered and a recommendation made with respect to each one. The outcome of the deliberations on agenda items 5 and 10 will be particularly relevant when making these recommendations. It may be necessary to have a transition period of support during which both the previous policies and the new policies are incorporated.

21. Budget for 1986/1987

Expenditures and obligations during the previous year will be reviewed and projections will be made for the next two years.

22. Any other business

22.1 Dates for future meetings

FAMILY HEALTH INTERNATIONAL

EVALUATION REPORT

FHI ASSISTANCE TO BKS PENFIN INDONESIA

December 1983

1. BACKGROUND TO EVALUATION AND TERMS OF REFERENCE

Family Health International (FHI) is committed to carrying out periodic field evaluations of all major FHI subgrants to Fertility Research Programs. With regard to the successive subgrants to the Coordinating Board for Fertility Research in Indonesia (BKS PENFIN), FHI has previously carried out annual evaluations utilizing FHI in-house personnel. For 1983, FHI decided to organize a comprehensive evaluation review of the program, utilizing external consultants.

A team of two consultants, Ms. Sharon Epstein and Dr. Martin Wingate, was recruited by FHI to conduct an evaluation over the period 18-29 August 1983 inclusive in Indonesia. Ms. Epstein's experience is in development and management of population, family planning and maternal and child health programs in developing countries. Dr. Wingate has had extensive experience in biomedical research related to reproductive health, obstetrics/gynecology and perinatology. The specific terms of reference for the evaluation were stated as follows:

1. Discuss with principal officers and the USAID population office, Jakarta (and other potential resource contacts) the goals and objectives of BKS PENFIN;

2. Based on the BKS PENFIN draft proposal and FHI revised version (together with FHI in-house budget plans), review the 1983-85 workplan and make recommendations vis-a-vis the appropriateness and adequacy of the new subgrant proposal;

3. Analyze current staffing pattern and changes implied in the new subgrant and make recommendations regarding actual needs -- if possible, obtain job descriptions of subgrant personnel;

4. Discuss workplan and needed inputs from FHI to accomplish it; develop workplan further to enable BKS PENFIN, with FHI assistance, to implement planned studies, analyze and interpret data, write study and consultant reports; also, develop workplan to include requested installation of additional microcomputers; suggest administrative needs to manage and track multi-source funding, allocate indirect costs, etc.;

5. With Dr. Wingate as the biomedical resource person, identify biomedical research needs, necessary clinical inputs, specific studies desired and needed training to carry out the above;

6. Generally, identify FHI training and transfer of technology opportunities; gather broad to specific ideas (formal proposals not expected);

7. To the extent possible, develop a five-year plan based on all of the above discussions, findings and recommendations; suggest longer-range commitments needed, financial requirements, training, workshops, studies, travel (both directions) and inter-relationships (FHI, BKKBN, USAID, etc.).

Ms. Epstein was requested by FHI to serve as primary evaluator and spokesperson for the evaluation team, and to coordinate the preparation of their report. Dr. Wingate was

asked to serve as the biomedical research resource person with special attention to objective 5.

This evaluation report reflects the findings and recommendations of the team as accepted by FHI.

2. PEOPLE MET IN THE COURSE OF THE EVALUATION AND PROCESS OF THE EVALUATION

A list of persons contacted by the evaluation team in Indonesia and persons who participated in briefing the evaluation team in the U.S.A. is included as Appendix I to this report. The list includes BKS PENFIN officers and staff in Bandung, Indonesia; officials of the Population and Family Planning Coordinating Board of the Government of Indonesia (BKKBN) and Ministry of Health (DEPKES), AID and UNFPA officials in Jakarta; staff of BKS PENFIN collaborating centers in Semarang and Jakarta; and FHI staff in the Research Triangle Park, North Carolina, U.S.A.

3. ORGANIZATION OF BKS PENFIN

A. Major Goal

The BKS PENFIN was established in 1977, by a group of obstetricians-gynecologists in order to develop a biomedical research capability in support of Indonesia's family planning program. BKS PENFIN's organizational priorities in support of this goal were stated to the evaluation team as follows: research in contraceptive methods, research in maternal and child health (MCH) monitoring and referral, research into new and improved drugs in contraception and reproductive health with appropriate clinical testing, training in research methods and techniques for Indonesian investigators, establishment of a computer capacity for data collection and analysis, training in data analysis, and wide dissemination of research findings to policy-makers and clinicians in Indonesia.

At the present time, after several years of assistance from FHI and other aid organizations and contractual arrangements with some pharmaceutical companies, BKS PENFIN is the strongest network in Indonesia for the implementation and coordination of biomedical research. The Chairman of the BKKBN, the Deputy/Population, and the Chief of the BKKBN Bureau for Research and Program Development stated this clearly to the evaluation team. This observation was borne out by the team's subsequent discussions with BKS PENFIN officers and staff, and others interested in biomedical research in fertility and contraception in Indonesia.

B. BKS PENFIN Secretariat

The Secretariat is located in Bandung, Indonesia, and is directed by a team of four non-salaried BKS PENFIN elected officers: a Chairman, Vice-Chairman (in Semarang, Indonesia), a Secretary-General and a Treasurer. All are distinguished obstetricians-gynecologists. The BKS PENFIN Chairman is also President of the Indonesian Society of Obstetrics and Gynecology.

The Secretariat is housed in the Obstetrics and Gynecology Department of Hasan Sadikin Hospital in Bandung (a teaching hospital, part of the Medical Faculty of the University of Indonesia), and occupies several rooms and some hall and storage space. In addition, the BKS PENFIN officers have their own offices in the hospital as members of the Medical Faculty. BKS PENFIN employs a number of paid staff on a fixed term basis and operates a microcomputer from these premises.

BKS PENFIN is governed by a Board that meets every year. Collaborating research centers in the network, not individuals, are members of the organization. A Medical Committee meets twice a year (three OB/GYN members and the head of the local Health Department). A Scientific Committee, which decides specific research priorities, meets as required (three OB/GYN members), and a Human Protection Committee meets once a year (four "community" members, that is, an educator, religious leader, sociologist and lawyer). A Nominating Committee meets once before each General Assembly and on an ad hoc basis. Periodically, membership in all committees is changed by election.

BKS PENFIN holds a major General Assembly, at which decisions on its constitution and bylaws are made. General Assembly meetings are held infrequently -- the last took place in 1982, five years after formation of the organization, and the next was scheduled to take place three years later. An Annual Meeting is held for BKS PENFIN collaborators and other research investigators in Indonesia. Other meetings, such as peer reviews for particular research, are held with BKS collaborators during each year. A quarterly Newsletter was started in 1982.

C. BKS PENFIN Research Network

BKS PENFIN has organized an impressive network of twelve collaborating research centers located in Sumatra (north, south and west), Java (east, west and central), Bali and Sulawesi (north and south). A map of the locations of the centers is attached to this report as Appendix II. Each center is an integral part of the OB/GYN Department of major University of Indonesia teaching hospitals. A number of family planning clinics (from 2 to 15 respectively, geographically dispersed away from the centers) associated with each center participate, under supervision, in data collection for BKS PENFIN research. A total of 65 clinics have been active in research so far.

A distinguished associate physician of each OB/GYN Department (usually the Chairman) is in charge of each collaborating center as Chairman, but a number of specialist-physicians in the OB/GYN Department can participate in BKS PENFIN-stimulated research. A center is staffed by at least the Chairman, a Secretary and two staff who participate as investigators.

Sister/midwives and other staff associated with the OB/GYN Departments and the family planning clinics collaborate in data collection under the direction of the Chairman of the collaborating center or the research coordinator.

All medical personnel who are members of BKS PENFIN or who are drawn into research are Government servants (working in Government facilities)* who have clinical responsibilities during the working day. The specialist OB/GYNs also have private practices, usually held in the evening. BKS PENFIN research is carried out in addition to or in tandem with these responsibilities. It is a tribute to the strength of interest in research that time constraints were not overly stressed by the specialist-physicians. The research may answer important patient-care and

* In contrast to hired Secretariat staff in Bandung who are not employees of Government but of BKS PENFIN.

clinical questions, as well as address maternal and child health and family planning (MCH/FP) policy and program issues. The centers are able to draw on the facilities of their host OB/GYN Departments for staff time, premises, equipment and supplies and other administrative support. Collaborating centers reimburse some part of these expenses through payments received from the BKS PENFIN Secretariat for completion of study forms, but the OB/GYN Departments probably contribute more than they receive. BKS PENFIN can make these "forms payments" or "service payments" depending upon the arrangement it negotiates with a donor agency or pharmaceutical company for a particular piece of research.

The BKS PENFIN Secretariat negotiates for research support with outside organizations on behalf of the network. It serves as an intermediary for the network with Government - primarily the BKKBN and Ministry of Health. The Secretariat works with each center to build up its capacity to undertake research, particularly in terms of training in research methodology/design, in clinical studies and in biostatistical techniques. The Secretariat (advised and assisted by FHI) assists centers to adhere to research protocols, to establish a system of data collection and data checks, to process data utilizing the BKS PENFIN microcomputer provided by FHI, to analyze data and to disseminate research findings. There is much interchange between the Secretariat staff and collaborating center staff on data checks to ensure quality data collection. During a study, center staff are assisted by Secretariat staff to make appropriate and repetitive data checks on a periodic basis. Although BKS PENFIN pays close attention to assuring the quality of data collection, the team agreed with BKS PENFIN officers and FHI staff that in-country capacity to process and analyze data and to prepare final reports and disseminate the results should be further strengthened.

The evaluation team visited the collaborating center in Jakarta, in the OB/GYN Department in RSCM General Hospital, and the collaborating center in Semarang, in the OB/GYN Department of the Dr. Kariadi Hospital, to be briefed on the operations of a collaborating center and on the relationship of a collaborating center and the Secretariat. The Chairman of the Semarang center is also Vice-Chairman of BKS PENFIN. The team met with specialist-physicians at both centers who were participating in research, and visited two collaborating family planning clinics - the Tebet Clinic in Jakarta and the Musuk Clinic, about sixty miles from Semarang.

D. Expansion of the Network

Three or four new centers may eventually be added to the BKS PENFIN network. The Army General Hospital in Jakarta has already applied for membership and final agreement is pending. OB/GYN Departments of teaching hospitals in Irian Jaya, Ambon in Molucco, and Kalimantan have not yet applied but have expressed interest. These centers would add to the representativeness of the network in Indonesian terms. While their geographical areas and the communities they would serve are different from other large parts of the Indonesian population, they nonetheless would represent large, relatively stable populations which could be systematically traced for long-term epidemologic research. Consideration must also be given to the political importance of these populations. Therefore, BKS PENFIN is in the process of working with appropriate institutions in these areas to determine their research capacities and needs.

The evaluation team felt that BKS PENFIN realized that the capacities of the Secretariat could easily be over-extended if the system were expanded too rapidly. BKS PENFIN must consider what each additional center could marginally "cost" the network in terms of possible diminished supervision from the center and a decline in the quality of data. Staff time, travel funds, the capacity of the computer, and the strain on management systems are all important considerations. FHI is not eager

BKKBN and BKS PENFIN also acknowledged many personal staff contacts for implementation of particular studies to date, but both regretted insufficient formal meetings on a regular basis between both organizations. High BKKBN officials clearly stated their intention to improve the situation. The Chairman of the BKKBN has consulted the Society of Obstetricians and Gynecologists, among others, to advise him on resolving short-comings in coordination of biomedical research in general. By October/November 1983, a restructuring within BKKBN was to be concluded which, in the short run, will concentrate responsibility for biomedical research in fertility in a specific unit of the BKKBN. In the long run, perhaps to be negotiated over the coming year and concluded within three to four years, the intention was stated to establish a Biomedical Research Center (also called a "National Reproductive Research Center" in discussions within the BKKBN).

BKKBN has also undertaken discussions with the Geneva-based WHO Program in Training and Human Reproduction (HRP). The HRP Director, Dr. A. Kessler, recently visited Indonesia, during which time he helped the BKKBN draw up a project document for $422,000 in UNFPA funding over three years, along with WHO/HRP technical assistance, to strengthen the BKKBN in planning and coordination of biomedical research. This assistance, if approved, and the anticipated restructuring would seem to be complementary developments at the BKKBN.

There is some similarity -- as in other countries -- between WHO/HRP/UNFPA assistance and FHI assistance in biomedical research in fertility, and this case is no exception. Some of the assistance currently contemplated in the BKKBN/UNFPA/HRP proposal is very similar to what FHI has already made available to BKS PENFIN, which is hardly mentioned in the document (although BKKBN officials expressed to the evaluation team their intention to build on what they consider a strong existing network). The precise implications for the BKS PENFIN network is unclear.

What seems clear is the BKKBN's intention to exert its authority to plan, coordinate, and oversee the development of a research network in Indonesia and assistance from outside.

Notwithstanding this new emphasis on strengthening its coordinating role, there is a genuine respect on the part of BKKBN for the strong and imaginative development of BKS PENFIN, for the dedication, experience and capabilities in management of its Chairman and founder in particular, for the energy of its Secretary-General, for its ability to attract so much interest in research among OB/GYNs, and for its active work in creating a potential in the provinces to conduct quality biomedical research. The BKKBN has been very encouraged by the development of this non-governmental organization (NGO) which, in the words of one high official, is "the only organization that actually did the work" (by comparison with other NGOs) when called upon to undertake a project by BKKBN.

The BKKBN has been aware of FHI assistance to BKS PENFIN, although not perhaps in all of its details. As in the past, all FHI senior staff visiting the country (with exception of those who arrive to advise on specialized, technical areas) should seek to make contact with the BKKBN Chairman, the Vice Chairman for Administration and External Assistance (Dr. Peter Sumbung), the Deputy Population (Dr. Pardoko), the Director, Research and Development (Dr. Pudjo Ruhardjo), as well as the Chief of the Contraceptive Bureau (Dr. Sudomo). The evaluation team informed the Chairman of the BKKBN that, from its briefing at FHI, they had every reason to believe that FHI would be willing to assist in any way in the development of biomedical research in fertility in Indonesia and that the present subgrant assistance to BKS PENFIN did not necessarily represent a ceiling on FHI assistance to Indonesia - further assistance could possibly be considered and FHI staff would make further contact with the BKKBN to explore outstanding needs.

FHI intends to follow up on this point in correspondence and discussions.

In fact, FHI is working directly with BKKBN (e.g., nearly completed RAMOS project, planned long-term oral contraception follow-up study). The head of BKKBN's Contraceptive Technology Division (under the Bureau of Contraceptives), Dr. Hermini Sutedi, attended a two week workshop at FHI, September - October 1983, on contraceptive technology and clinical research methodology. By providing this training to a key BKKBN staff member, who is directly involved in monitoring BKKBN sponsored clinical trials (including BKS PENFIN work), FHI hopes to contribute to strengthening BKKBN capacity to coordinate biomedical research in Indonesia.

In 1981, in recognition of the development of the BKS PENFIN network, the BKKBN commissioned the organization to implement on its behalf a large comparative study of the safety, efficacy and acceptance of three brands of standard-dose oral contraceptives, three brands of low-dose OCs and four types of inter-uterine devices (IUDs), all presently available and in general use in Indonesia. This study is funded through the BKKBN by USAID utilizing bilateral population assistance funds.

After a preparatory period, data collection began in October 1982 and is proceeding without serious problems. BKS PENFIN feels that BKKBN/AID should consider increasing the budget for field worker travel and further training of field workers, so that the supervision of data collection can be given adequate attention. The evaluation team urged the Secretary-General of BKS PENFIN to discuss this important point with BKKBN and also with the AID Population Officer in Jakarta. Recruitment of IUD acceptors is on schedule but recruitment of OC acceptors has been slow because of current Government emphasis on IUD acceptance and the availability of OCs outside a clinic setting. The period in the project work plan allowed for OC acceptor recruitment will be extended to permit additional efforts by those or alternate clinics to meet OC acceptor targets. FHI suggestions to BKS PENFIN to improve recruitment have been considered and some have been implemented.

A Biomedical Research Steering Committee was established by the BKKBN, composed of BKKBN, Ministry of Health, University of Indonesia Faculty of Medicine and BKS PENFIN representatives to oversee the progress of the project and cope with any problems in implementation. The Committee was to meet at least four times a year, however, it has reportedly not met on schedule. BKS PENFIN feels the need for regular and perhaps more frequent meetings. Funds have not always flowed smoothly through the BKKBN to BKS PENFIN for special purposes, particularly to support travel for supervision of data collection. BKS PENFIN has had to utilize FHI core support funding to keep up the quality of supervision and to support other project activities. If FHI core support is used in this way, BKS PENFIN will ultimately be constrained in carrying out a larger work program in biomedical research, which it feels that it should have the capacity to undertake even while the BKKBN/AID-assisted project is ongoing. The high priority of the BKKBN/AID-assisted project is readily acknowledged by all concerned and the evaluation team stressed to the BKKBN and AID mission in its discussions that AID funds should flow more smoothly to BKS PENFIN.

In an earlier acknowledgement of BKS PENFIN strengths, in 1979 BKKBN requested BKS PENFIN to modify and extend MCM to lower levels of the West Java Province health system, to adapt the system to child care as well, and to develop referral forms for maternity care, child care and family planning which would improve overall patient care between referring and referral centers, including referrals by traditional birth attendents to peripheral centers. Project funding was requested from and approved by UNFPA for Phase I and II of the project, focussing on 22 regency

hospitals in West Java, and those phases have now been completed. UNFPA has recently indicated that it cannot assure funding for the last phase of the project and neither BKS PENFIN nor the BKKBN has yet decided what options exist for continuation of the project. FHI has not been directly consulted or involved in this project from a technical point of view in the past. Despite the fact that UNFPA cannot fund the project any longer, the UNFPA Coordinator informed the evaluation team that a UNFPA-assisted meeting to review the project to date will be held in November or December.

The Ministry of Health suffers some division of opinion on the usefulness of extention of maternal and child care monitoring as a project. The MCH Sub-Directorate has expressed interest in having BKS PENFIN undertake a similar project to the one discussed above, thus extending the system to lower levels in the health hierarchy, and involving TBAs in risk assessment and referral. This latter project was discussed in terms of implementation in four provinces: West Java, Central Java, Yogyakarta and North Sumatra, with a pilot project in the first year to be initiated in West Java. The Director-General of the Research and Development Board of the Ministry (also interviewed by the evaluation team) appeared uninterested in application of the MCM approach and implied that execution of the MCM approach would duplicate further attempts to improve and utilize the Ministry's regular system of reporting on maternal and child health.

It is of particular concern that BKKBN, the Ministry of Health and BKS PENFIN have apparently not yet met together to discuss two very similar projects. FHI recommends that such a meeting be organized as soon as possible to define important questions that remain unanswered by data generated under this sort of project. The Ministry of Health should be informed by BKS PENFIN of the objectives and results in data collection to date under Phases I and II of the BKKBN/UNFPA-assisted project. Potential donors will most likely want the two projects reconciled before commitments are made.

5. RELATIONSHIP OF BKS PENFIN AND IFRP/FHI, AND FUNDING HISTORY

From 1977 to 1981, IFRP was the major source of support for biomedical research in Indonesia related to fertility issues. The ideas for particular studies were, for the most part, initiated and proposed by IFRP in consultation with potential investigators in Indonesia, and the U.S.-based organization played a major role in developing research protocols and research strategies. At first, IFRP assistance was provided for individual studies, largely on the basis of forms payments, and was negotiated with BKS PENFIN members or other Indonesian investigators on a contract-by-contract basis.

From 1981, although contract research continued to be approved, FHI assistance was largely provided under annual subgrants to BKS PENFIN. The purpose was to strengthen BKS PENFIN as a standing Indonesian research institution therefore permitting it to develop its relationship with Government, to develop research concepts related to the needs of the Indonesian family planning program, to carry out research studies through a network of collaborating centers throughout Indonesia, process data in-country, train and upgrade research skills of network investigators and staff, and disseminate research findings.

FHI provided $150,320 from May 1981 through September 1982 and $75,000 from October 1982 through September 1983 for research forms payments (1981/82 only), staff salaries, some professional and consultant fees, expenses of in-country travel to supervise ongoing research, costs of professional meetings and meetings of research network collaborators, external training for selected investigators and staff at FHI in the USA and expenses of in-country training workshops. From May 1981 through September 1982, FHI also utilized in-house resources (extra to the subgrant budgets) to provide the BKS PENFIN

Secretariat with a microcomputer capability for local data processing and analysis in Bandung, computer software and advisory services; services of the FHI computer facility in the U.S.A.; and other advisory services from FHI scientists and staff.

FHI has indicated its willingness to continue providing core support and technical assistance for an additional period of two years, from October 1983 through September 1985. An interim subgrant has been made for the first four months of this period, pending certain revisions of the original two-year proposal as a result of the evaluation team's discussions with AID/Jakarta and report to FHI. Some increases in the level of FHI support have been projected by FHI and supported by the evaluation team's recommendations. A copy of the new subgrant proposal, revised somewhat in response to the evaluation findings and recommendations, is attached.

6. COMMENTS ON PROPOSED TWO-YEAR SUBGRANT, 1983-85

The evaluation team found that the original proposal did not reflect completely the full range of BKS PENFIN activities which would be supported by FHI core support and technical assistance. On the other hand, some of the studies presented by BKS PENFIN as on-going activities are either no longer active or were scheduled to be completed by the time of initiation of the new subgrant. Some BKS PENFIN activities (with direct funding from other sources) were previously unknown to FHI. FHI agrees that the subgrant proposals for core support should describe the entirety of BKS PENFIN activities. Improved reporting by BKS PENFIN and better surveillance by FHI are required in the future.

With respect to service-related research, the evaluation team was unable to fully clarify the relationship between two seemingly similar maternal care monitoring (MCM) projects included in the original proposal. BKS PENFIN included completion of the UNFPA funded project (at 22 regency hospitals in West Java) and initiation of a complementary project for the Ministry of Health in its proposed work program. As noted above, UNFPA has declined to fund the third phase of the MCM project and the Ministry of Health project seems far from definite at this point. BKS PENFIN feels confident in its ability to manage and implement all of the proposed biomedical and service-related research (and even initiate a limited number of additional biomedical studies over the next two years). While FHI agrees that BKS PENFIN has been a good judge of its own capabilities, the evaluation team felt that the West Java MCM project could be potentially overwhelming in terms of staff and computer time. Assuming the project's final phase is eventually funded, BKS PENFIN and BKKBN should specify precise objectives for the project and parameters of BKS PENFIN involvement. Meanwhile, BKS PENFIN should continue to give emphasis to its area of greatest strength and original purpose, biomedical research; while the Government should increasingly take on responsibility for improving the nation's MCH data collection system.

In addition to the specific studies to be carried out under the new subgrant, BKS PENFIN plans to hold in-country training in research methods, data processing, and data analysis and conferences to disseminate research findings as studies reach their final phases. BKS PENFIN and FHI are also planning to develop data processing capabilities by upgrading the microcomputer at Bandung and reviewing utilization plans for proposed placements of additional microcomputers to selected centers of the BKS PENFIN network. BKS PENFIN's request for several additional microcomputers has been acknowledged, with considerable interest on FHI's part, but cannot be properly evaluated without more specific justification, including center-specific utilization plans.

7. PROPOSED NEW RESEARCH FOR TWO-YEAR SUBGRANT PERIOD AND FOR FIVE-YEAR PLANNING PERIOD

FHI is prepared to consider additional assistance for new biomedical research, to be initiated over the next two years and beyond. The evaluation team discussed outstanding research concerns with a variety of contacts at BKS PENFIN, BKKBN, Ministry of Health, and USAID. A framework of thirteen research concerns which could be addressed by BKS PENFIN over a five year period was produced and is attached as Appendix III. FHI has asked BKS PENFIN to review this framework (within its network and with Government) to try to establish its research priorities and then submit at least rough proposals to FHI as soon as possible.

Both BKS PENFIN and FHI are interested in developing long-term epidemiological studies, particularly with reference to safety, effectiveness and acceptability of contraceptives presently in use. The BKKBN has indicated an interest to FHI in a long-term OC follow-up study. BKS PENFIN suggested some other study areas to the evaluation team as well, for example: the relationship between diseases peculiar to Indonesia and the effect of contraceptive methods, the relationship between nutritional factors and contraception, and some sociological questions regarding contraceptive acceptance.

FHI recommends that BKS PENFIN (with FHI assistance) design a training course for BKS PENFIN investigators and BKKBN representatives around the development of an actual long-term study, whereby the research protocol would be drafted during the course by the participants. FHI should continue to work with BKS PENFIN to improve longer range planning and to strengthen skills and experience in formulating sound research proposals and protocols of all types.

8. REQUIREMENTS FOR IMPLEMENTATION OF TWO-YEAR SUBGRANT AND FIVE-YEAR WORK PROGRAM

Both BKS PENFIN and FHI agree that BKS PENFIN must be strengthened in analysis of research data, in report-writing and in dissemination of research results. Strengthening these three areas in particular is crucial to the full acceptance of BKS PENFIN as a reputable research institution within Indonesia and internationally. In addition, FHI feels that planning and management of research, and the day-to-day administration of the BKS PENFIN organization, need attention.

A. Analysis of Research Data

The evaluation team strongly supported an earlier FHI proposal that BKS PENFIN establish two new staff positions of Executive Director or Senior Program Officer, and Information Coordinator. Vigorous efforts to recruit individuals with strong academic records in relevant disciplines;with some work experience, preferably in management, analysis of data and information/communication activities respectively; with spoken and written fluency in Bhasa Indonesian and English;and with writing and communication skills; should be made immediately by BKS PENFIN officers. FHI will work with BKS PENFIN to train the new staff, both in Bandung and in the U.S. The new staff will be trained in interpretation of research data including tests of significance, in analysis of computerized data sets and in the mechanics of report-writing to an internationally acceptable standard, and each will be associated with counter-part FHI staff in the U.S. who are themselves skilled in analysis and presentation of OC, IUD and other clinical trials data. FHI has expressed willingness to make funds available for both the new posts and for training, and appropriate line items are included in the proposed subgrant and the FHI in-house budget.

Funds under Statistical Services (Consultant/Professional Fees) in the proposed

subgrant should also be used by BKS PENFIN to engage Indonesian scientists on a short-term basis to help BKS PENFIN investigators and staff work on analysis of particular data sets. Affiliations between biostatistics and epidemiology departments (and other disciplines) of relevant Indonesian institutions and BKS PENFIN both in Bandung and at the level of collaborating centers, should be negotiated. These specialists should be involved in BKS PENFIN training courses on a co-teacher basis if possible.

B. Report-writing and Dissemination of Research Results

These skills can be taught to both new staff, but the Information Coordinator should be largely responsible in these areas and thus must have strong writing skills in both Bhasa Indonesian and English. The BKS PENFIN Newsletter should be directed specifically at mid-level service personnel in the MCH/FP programs, and should aim at interpreting pertinent new developments in biomedical research in fertility for them in language they can understand, particularly the results of Indonesian research studies but also including international developments. BKS PENFIN, and the new Information Coordinator particularly, should consider two other publications on a regular basis, and their wide dissemination to those actually involved in research, to those who may become involved in future and to MCH/FP policy-makers in Government. One publication would be the proceedings of any relevant BKS PENFIN meeting, conference or workshop. The other publication would be a biannual compilation of short abstracts of completed, ongoing and proposed biomedical research studies in fertility and human reproduction - whether conducted through the BKS PENFIN network or by other investigators in Indonesia - designating study title, investigator and how to contact him or her, starting date, estimated completion date, study question or hypothesis, description of study design, stage research is in and results or status to date. Individual distribution lists for each of these three publications should be carefully developed so that interested and influential individuals and institutions receive copies of those publications which are of most use.

C. Management and Administration

The present Chairman of BKS PENFIN has been re-elected to continue his strong direction of the organization for another three years. He may retire from Government service in this period but he fully intends to continue his work with BKS PENFIN.

The Chairman has indicated that BKS PENFIN would prefer to hire and train a "Senior Program Officer" (rather than an "Executive Director"), and that the BKS PENFIN Secretary-General will continue to play a strong role in planning, management and administration. The Secretary-General has been exceptionally vigorous and talented in support of the organization's goals and programs, and her active participation in future is essential to the continued success of BKS PENFIN. Nevertheless, FHI had previously indicated to BKS PENFIN and the evaluation team agreed, that the BKS PENFIN work program, support staff and the complexity and size of the budget have grown to such an extent that the Advisory Committee, Chairman and Secretary-General - all of whom divide their time between public and private clinical responsibilities, their own research interests and participation in BKS PENFIN management - need the assistance of a senior, full-time staff member in overseeing research and support functions, and in ensuring financial and other accountability to those agencies assisting BKS PENFIN. FHI strongly urges that BKS PENFIN hire the Senior

Program Officer, with the full intention of investing that person with the considerable responsibility of an executive officer - that is, of helping BKS PENFIN committees plan for the future, with the coordination of research activities which are on-going, and with the direction of BKS PENFIN staff on a daily basis to support all the major activities of the organization. The Senior Program Officer, working with the Secretary-General, Treasurer and Accountant, must have a clear overall understanding of the budget, all sources of funding to BKS PENFIN and accounting requirements of each major contributor.

D. Staffing

Updated job descriptions for BKS PENFIN salaried and non-salaried staff were provided to the evaluation team as requested. The staffing of the organization needs some clarification as soon as possible. The evaluation team recommended that FHI use its in-house budget to employ directly, on behalf of FHI, a short-term management analyst, with accounting skills, from a reputable Indonesian management/accounting firm to work with BKS PENFIN in Bandung to clarify staffing arrnagements, to strengthen job descriptions which presently overlap, and to improve the present accounting system both with respect to salaries/benefits and individual research studies. The AID mission, Jakarta, has suggested appropriate consultant firms to the evaluation team. The FHI program coordinator should explore the feasibility and costs of carrying out this recommendation on his next visit to Indonesia.

At present, thirteen full-time and four part-time salaried posts, all supported by FHI, exist in BKS PENFIN. One post-"Program Officer"- is vacant. The BKS PENFIN proposed subgrant showed only nine existing posts. BKS PENFIN, under pressure of work during previous subgrant periods - particularly under pressure to supervise data collection in the field - has split the approved budgeted amounts for salary/benefits and has utilized approved funds under "Programming Services" and "Information Services" to create several additional staff posts. It should be immediately emphasized that this has been done in good faith without overspending the budget approved by FHI and AID. BKS PENFIN was advised by the evaluation team that this was nevertheless an incorrect procedure, despite what appeared to the team to be a real need for the additional posts.

The evaluation team reviewed present and future staff needs with BKS PENFIN officers and its recommendations for staffing pattern is reflected in the attached revised subgrant proposal.

E. Facilities

BKS PENFIN has been housed in the OB/GYN Department of Hasan Sadikin Hospital in Bandung, University of Indonesia, where its senior officers are members of the Faculty of Medicine. FHI has provided for modest prorated rental of rooms, utilities and maintenance under the hospital's operating budget. The Chairman of BKS PENFIN informed the evaluation team that the organization has been under pressure by hospital administrators to vacate the rooms it occupies. BKS PENFIN submitted a substantial request for rental of new premises in Bandung, for utilities and maintenance, and for furnishings, to the evaluation team for consideration by FHI for funding. This had not been included in the BKS PENFIN's formal request for continued funding, 1983-85. While FHI acknowledges that space is becoming increasingly tight, FHI prefers to apply any increases in available funds for BKS PENFIN to areas of technical assistance and training. Ultimately, BKS PENFIN will have to absorb more of its own core costs, including rent; and FHI is reluctant to promote a move to much more expensive quarters. Perhaps other arrangements, involving only

modest increase in rent, could be discussed with Hasan Sadikin Hospital for increasing space available to BKS PENFIN.

F. Microcomputer Facilities

The BKS PENFIN Data Processing Manager, in charge of the Texas Instruments (TI) Model One microcomputer, described to the evaluation team the great value of the training received through the in-country course arranged by the FHI Director of Scientific Support Systems during the last subgrant period, and the value of the microcomputer itself. The evaluation team agreed that the microcomputer and related software provided to date has strengthened BKS PENFIN in introducing standardization of data, in improving quality control of data, and in reducing the need for tabulation of data in the U.S. on the FHI computer. In future, the microcomputer facility can be used for training purposes as well, particularly in data analysis and composition of reports.

The present microcomputer capacity will be enhanced during the period of the proposed subgrant. The TI-1 will be replaced by a Model TI-352, with greater memory and capacity (and probably with a TI-352 unit with multiple terminals, for greater access and training purposes).

As discussed above, the question of placing additional microcomputers at selected BKS PENFIN centers will be carefully reviewed, with the assistance of FHI's Director of Scientific Support Services.

The question of availability, adequacy, and affordability of maintenance and repair services for TI microcomputers in Indonesia needs, and is receiving, urgent attention. FHI is working with Texas Instruments Corp. and its Jakarta representative to resolve past difficulties.

The larger question of appropriateness of the TI (as opposed to other brands) is a corporate matter for FHI which needs to be reviewed in a larger context than that of Indonesia alone. The evaluation team, reflecting concerns expressed by both BKS PENFIN and the AID/Jakarta Mission, raised this issue with FHI; and the FHI Director of Scientific Support Services will discuss this with all concerned on his next visit to Indonesia.

G. Training

Training is provided for in several ways under the proposed subgrant. FHI staff will be matched up with BKS PENFIN staff and investigators for training in particular areas; for example, the Senior Program Officer and Information Coordinator will be matched up with respective FHI staff responsible for analyzing data writing final study reports on clinical trials with OCs, IUDs, etc. If these FHI "counterpart" staff must visit Indonesia, their expenses will be provided for under the FHI in-house budget.

Second, FHI will continue to bring a small number of selected investigators to FHI Headquarters to participate in workshops of several seeks' duration arranged on several topics. These investigators may or may not be part of the BKS PENFIN network at present. Funding is arranged separate to the subgrant budget itself. Shortly after recruitment by BKS PENFIN, the Senior Program Officer will be trained at FHI Headquarters as well. Funding for that trip is provided under the subgrant.

Third, in-country training workshops, to be conducted with FHI technical staff assistance, are included in the proposed subgrant. A fresh discussion and review of the appropriate number of workshops and subjects to be covered over the next two years should be conducted by the FHI Program Coordinator on his next visit. An epidemiological research workshop has already been suggested. A follow-up workshop on statistical methods (to continue the training provided under the previous subgrant) has also been suggested and should be considered. In these and other potential areas of in-country training, FHI and BKS PENFIN should explore possibilities for utilizing Indonesian biostatisticians and epidemiologists as co-teachers.

As BKS PENFIN develops its plans for initiating additional biomedical studies (from the framework or as other proposals arise), additional workshops might be planned and designed around the specific research protocol to be developed and initiated.

8. ISSUES OF FINANCIAL SELF-SUFFICIENCY AND CORE SUPPORT

AID/Washington and FHI have certain concerns about the growth of the core support budget for BKS PENFIN, and FHI asked the evaluation team to consider the issue of eventual financial self-sufficiency for the organization and, in the short run, the gradual replacement of FHI assistance on a phased basis with other sources of funds.

FHI has raised the issue with BKS PENFIN and, over time, BKS PENFIN has succeeded admirably in attracting sub-contracts for particular research from a number of sources: the BKKBN, the IDRC and pharmaceutical companies. A close review of the budgets for each of the sub-contracts reveals that what FHI and AID/Washington term "core costs" are, in fact, provided for to a certain extent under some of the sub-contracts, including the projects for Government, but only for the duration of the individual study. Other costs, such as General Administration (including rent, etc.) are not addressed in those study budgets and, consequently, FHI core assistance in those areas is at present essential to keep BKS PENFIN going. Whether BKS PENFIN can negotiate some funding for these needs, on a prorated basis, with each sub-contractor is hard to determine. Certainly, the concept of prorated costs should be clarified within BKS PENFIN and it should be considered whether the BKKBN, IDRC, the pharmaceutical companies or other, future sub-contractors can be approached for such needs. It has been suggested that FHI consider engaging a short-term Indonesian consultant in management and accounting to assist BKS PENFIN review and clarify these issues.

In general, however, the options for BKS PENFIN to offset FHI assistance, both for core costs and for research studies, are limited. The degree to which BKS PENFIN can solicit sub-contracts or other funding from pharmaceutical companies without compromising its reputation for objectivity is a serious concern expressed by BKS PENFIN, AID/Jakarta, and the evaluation team.

There is a challenge to all concerned to come up with feasible alternatives to FHI support. Substitution of FHI support with the support of another external donor agency, even if it could be negotiated, is no solution at all. It is extremely difficult to think of ways whereby an organization concerned with biomedical research can generate income, when compared with an organization offering services.

BKKBN, with AID assistance is funding implementation by BKS PENFIN of the large Biomedical Project, and is contributing toward some "core costs" of BKS PENFIN (some employment of staff and travel for supervisory purposes, etc.). At the moment, the

funds are not being channeled smoothly from AID through BKKBN to BKS PENFIN, and this must be resolved. Whether BKKBN would contribute toward the "establishment" part of core costs in future to maintain BKS PENFIN was unclear to the evaluation team. For one thing, BKKBN has not been approached on the subject. In any case, the Government of Indonesia still receives large-scale external assistance for its population program. Under these circumstances the concept of financial self-sufficiency becomes somewhat clouded.

FHI is striving to help BKS PENFIN achieve the technical and administrative competence necessary to attract contract research work funded from a variety of sources, including FHI itself. As BKS PENFIN's abilities increase, FHI should increasingly fund research by BKS PENFIN rather than the strengthening of BKS PENFIN as an institution. Such a shift from institutional development grant to research contract may be a good measure of self-sufficiency, and FHI should explore additional opportunities for contracting more work with BKS PENFIN in the future.

FHI, with AID concurrence, has embarked upon a program of institutional development to create a capacity to undertake biomedical research in fertility in Indonesia. FHI has assisted BKS PENFIN with its core costs since 1981. The evaluation team found, and FHI agrees, that: it is too early to expect the Government to assume the burden of funding, that FHI assistance should continue and be supplemented over the next subgrant period to further strengthen technical and managerial capacity, that FHI should consider BKS PENFIN's ability to undertake more research work under contract, and that discussions with concerned parties regarding long range BKS PENFIN financing should continue.

Appendix I

Persons Contacted by Evaluation Team

INDONESIA

Bandung: BKS PENFIN Officers

Professor Dr. Sulaiman Sastrawinata, Chairman

Dr. Tina Agoestina, Secretary General

Dr. H. Hidayat Wijayonegara, Treasurer

Dr. Ariawan Soejoenoes, Vice Chairman (Samerang)

BKS PENFIN Staff

Miss Ati Suginati Permana, Assistant Program Officer

Mrs. Hadiati, Data Collection Coordinator

Mr. Agoeskanda, Data Processing Manager and Programmer (present responsibilities)

Mr. Arif, Systems Analyst

Mr. Agos, Computer Operator

Mrs. Dina, Secretary in Computer Unit

Note:

Other staff were introduced as evaluation team walked through BKS PENFIN offices. (See Appendix 8 for more complete listing of staff.)

Samerang: BKS PENFIN Collaborating Center Staff

Dr. Untung Praptoharjo, Chairman, OBGYN Department, Dr. Kariadi Hospital

Dr. Ariawan Soejoenes, Director, Village Project of the Medical Faculty, and Columbia University Project on Iron Supplementation

Dr. Sutoto, Oncology - Gynecology

Dr. Siti Mutmainnah Prihadi, Family Planning

Notes:

Musuk Clinic, 60 miles from Samerang was visited; the clinic physician and sister-midwife were interviewed.

Dr. Ariawan is also Vice-Chairman of BKS PENFIN

Jakarta: BKKBN

Dr. Haryono Suyono, Chairman

Dr. Henry Pardoko, Deputy, Population

Dr. Pudjo Ruhardjo, Chief, Bureau of Research and Program Development

Dr. Sunarti Sudomo, Chief, Bureau of Contraceptives

Dr. Hermini Sudeti, Bureau of Contraceptives (in Chapel Hill, U.S.A.)

Ministry of Health (Indonesian Acronym: DEPTKES)

Dr. A. A. Loedin, Director General, Research and Development

Dr. Suwarna, Chief, MCH Subdirectorate

AID Mission

David Piet, Population Officer

Rebecca Cohen, Associate Population Officer

Mrs. Molly Mayo Gingerich, Health Officer

Dr. Sonia Ruhardjo, AID Adviser to BKKBN on Nutrition and, in future, Liaison on Population Research

UNFPA

Miss Kazuko Kano, UNDP Deputy Resident Representative and Senior Population Adviser (i.e. UNFPA Coordinator)

Others in Jakarta

Dr. Firman Lubis, Executive Director, Yayasan Kusuma Buana (YKB)

Dr. R. S. Samil, Head of OBGYN Department, RSCM General Hospital, Faculty of Medicine, University of Indonesia*

Dr. Gulardi, BKS PENFIN Investigator

Dr. Trijatmo, BKS PENFIN Investigator

Dr. Biran Affandi, Subdivion of Human Reproduction, Department of OBGYN, School of Medicine, Raden Saleh Clinic, University of Indonesia

*BKS PENFIN Collaborating Center

Note:

Team visited Tebet Maternity Clinic in Jakarta and met with FP Physician in Charge, Dr. Uut (Government clinic; one of the clinics associated with RSCM General Hospital's OBGYN Dept., a collaborating center of BKS PENFIN).

USA

Research Triangle Park, North Carolina:

Family Health International

Dr. Malcolm Potts, President

Dr. Pouru Bhiwandiwala, Medical Director and Director, Task Force on Training and Transfer of Technology

Mr. Peter Miller, Senior Researcher, Training and Technology

Mr. Mark Robbins, Program Coordinator, Training and Technology (referred to in this report as Regional Coordinator covering Indonesia)

Dr. Michael Rosenberg, Medical Epidemiologist

Dr. Stephen Mumford, Senior Researcher, Clinical Trials

Dr. Judith Fortney, Senior Researcher, Contraceptive Safety Research

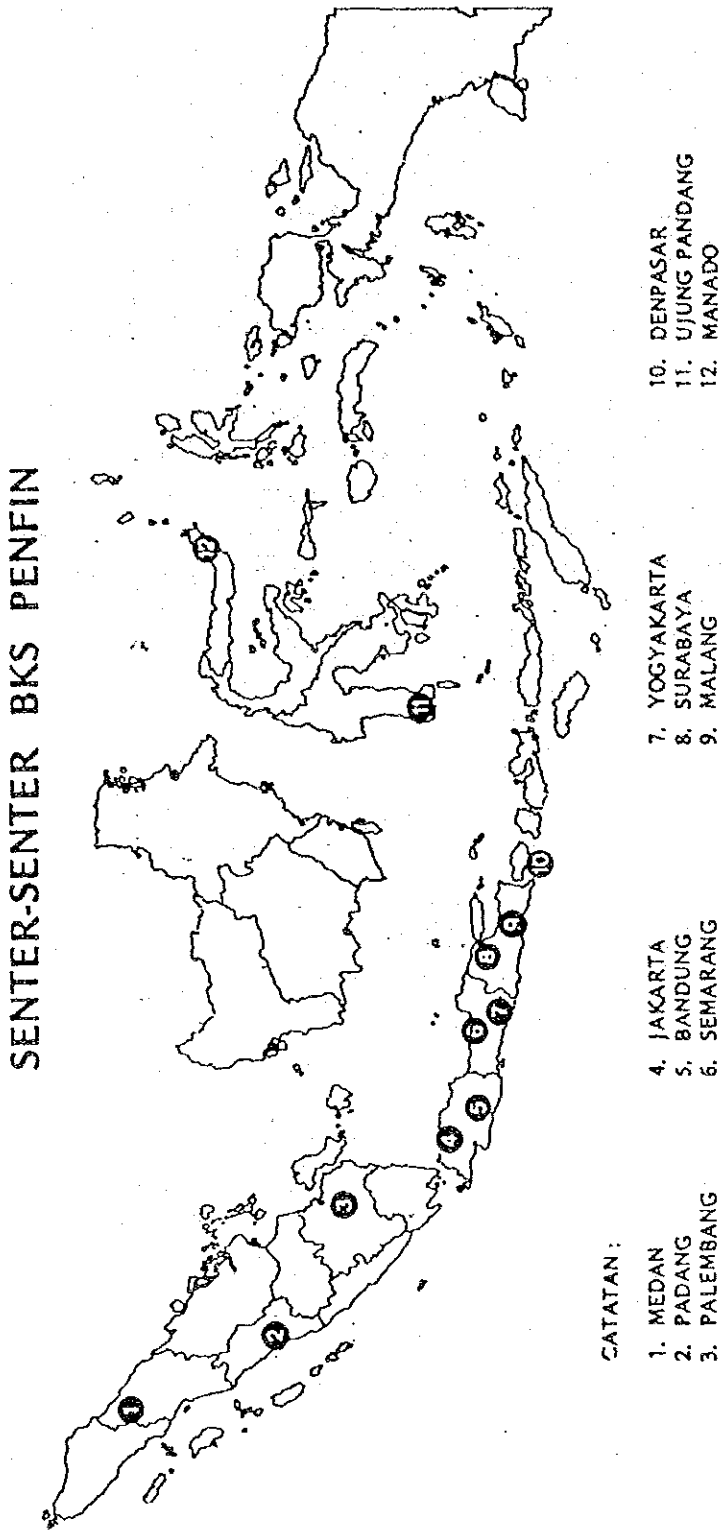
Dr. Barbara Janowitz, Director, Health and Demographic Research

Mr. Sandor Balogh, Senior Research Analyst, Clinical Trials

Dr. Pat Friel, Program Coordinator for Egypt, Training and Technology (formerly Regional Coordinator covering Indonesia)

Appendix II

MAP OF BKS PENFIN COLLABORATING CENTERS



FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
1. Progesterone-only OC (minipill) in breast-feeding women	Effects on: (a) Milk volume (b) Constituents/quality of milk (c) Acceptability and effectiveness as method of contraception (d) Neonate and infant: e.g. weight, diarrhea (e) Mother: e.g. thrombosis, menstruation	Straight or Comparative, with two brands and/or IUD	3 months 6 months Protocol ↓ Agreement ↓ Supplies + Contact for milk analysis with lab Training - BKS PENFIN	Each 3 months for 2 years	300 straight 200 each group Comparative	F.H.I. ⟶ BKS PENFIN ⟶ Min. Health ⟶ (MCH Subdirectorate)	High Medium Medium to low
2. Quinacrine Insertion for sterilization	(a) Safe and effective means of tubal-occlusion-faster, easier than tubal ligation (b) Clinic outpatient procedure	Straight	3 months ↓ Protocol ↓ Agreement ↓ Supplies and training Data analysis	Each 3 months for 2-5 years	500+	F.H.I. ⟶ BKS PENFIN ⟶	High High
3. Norplant Long term follow up	(a) Acceptability (b) Menstrual pattern changes (c) Use of fewer implants (d) Different configurations e.g. Micro spheres (e) Removal problems and identification after implant (f) Effectiveness over 5 years (g) New method of insertion	Straight and Comparative of Norplant I versus II* *I=6 implants II=2 implants	3 months Need stable population Training as needed Protocol ↓ Agreement ↓ Supplies and training Data analysis	5 years	500+	F.H.I. ⟶ BKKBN ⟶ (safety) Min. of Health ⟶ BKS PENFIN ⟶	High High High High

FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
4. OCs with and without iron	Iron in OC pack may reduce acceptance due to GI disturbances 60% women have Hb ↓ 10 Gms	Comparative 28 day OCs, last 7 pills with iron, or 21 day OCs	Immediate ↓ Protocol ready (FHI) ↓ Agreement ↓ Supplies ↓ Data analysis	1 year	100 each group	F.H.I. ⟶ BKS PENFIN ⟶	Medium Medium
5. Diet and breast feeding	Low protein, High CH, High fat, or Multiples Affects quality and quantity of breast milk	Comparative Diet histories and assessment Breast milk and infant feeding assessment (WT. gain), etc.	Comparative 3 months Dieticians Protocol for illiterates and literates Agreement Data analysis	2-5 years	Large numbers Minimum 300 each group	Min. Health ⟶ BKKBN ⟶ F.H.I. ⟶	High (particularly) re: village population High (particularly) re: village population Moderate to low
6. High risk profile for trophoblastic disease	Identify high risk women ↓ Earlier intervention Reduce (?) risk of choriocarcinoma	Straight Retrospective Current prospective	Immediate Protocol [illegible] ↓ Analysis	2 years	500 retrospective + Current	BKS PENFIN ⟶ F.H.I. ⟶	High High *

* Would be considered only if private funding could be raised by FHI

FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
10. Determinants of contraceptive choice in Indonesia	Why do women choose or reject a particular contraceptive method in Indonesia?	Straight Survey of clients	Immediate Protocol, simple	1 year	300	F.H.I. ⟶ BKS PENFIN ⟶ BKKBN ⟶	Medium High High
11. Pregnancy diet and outcome, particularly in village	High risk factors in Indonesia (a) Premature labor (b) Stillbirths (c) Infant & neonatal mortality and morbidity (d) Trophoblastic disease	Use trained dietitians, or train Develop protocol Follow outcomes	3 months+ Identify and further train dietitians * Develop protocols ↓ Agreement Data storage and analysis on regional microcomputers	5 years	10,000-50,000	BKS PENFIN ⟶ Min. Health ⟶ BKKBN ⟶ F.H.I. ⟶	High High High Medium
12. Ultrasonic fetal growth mensuration in Indonesia (MCH-related)	Significant discrepancy noted in fetal growth estimates when using U.S. mensuration data (BPD, thorax, abdomen	Computer analysis of data. Development of formula for Indonesia Wt. born< determinations	Immediate + more training for BKS PENFIN specialist	2-5 years	1,000	BKS PENFIN ⟶ F.H.I. ⟶	High Medium
13. Best contraceptive technique to use in delaying first pregnancy	Early marriage and Government + President urging delay 1st pregnancy to control family size.	Comparative study OC, Vaginal ring, injectable implant, other	As soon as possible Protocol ↓ Agreement ↓ Supplies Sociologist, Demographers, field workers Conference & training	2 years	Newly weds, as many as possible	President Min. Health BKKBN BKS PINFIN F.H.I.	High Top Priority

NOTE: The evaluation team perceived no immediate interest in participation in drug trials except insofar as these bear a direct relationship to Indonesian health and family planning concerns.

FRAMEWORK FOR POSSIBLE RESEARCH OVER FIVE YEARS

PROJECT TITLE	HYPOTHESIS	METHOD	START-UP AND NEEDS	FOLLOW UP/ YEARS	NUMBERS	ORGANIZATIONS INTERESTED	PRIORITY INTEREST
7. MCH profile for early detection of high risk pregnancy (Continuation of previous work on MCH)	(a) Need to identify high-risk pregnancies particularly in villages (b) Develop protocol for use by field workers	(a) Straight Outcome analysis by computer (b) Develop profile	Analysis of available MCH data Develop profile Develop simple data forms Train health workers in villages Develop training Develop transfer systems Set up consultation mechanism Protocols ↓ Agreement	5 years Place computers, software in regional centers Training: (a) Field workers (b) computer personnel in regions (c) re: data transfer systems	5,000+	F.H.I. ——→ BKS PENFIN——→ BKKBN ——→ Min. of Health→ UNFPA ——→	High-Medium High High High Unknown*
						* UNFPA has funded an MCH data collection project at regency hospital level; continued funding for last phase disapproved (see text of this report)	
8. Radio-immunoassay standardization	Need for standardization, and training lab personnel for Indonesian populations Prolactin, FSH, LH, Hcg, etc.	Train personnal and set up standards	Immediate Consultants, Supplies, Training in U.S.	Continuous	—	F.H.I. ——→ BKS PENFIN——→ Min. of Health→	Supportive* High High
						* FHI willing to serve as an intermediary to locate assistance from other sources.	
9. New drug delivery systems e.g. injectables (microcapsules)	Apply new delivery systems to hormonal construction as they arise, e.g. Insulin, nitrates	Straight then Comparative	New systems, Modified or invented	--	--	F.H.I. BKS PENFIN Min. of Health BKKBN	Medium to Low