

AGENCY FOR INTERNATIONAL DEVELOPMENT
PROJECT DATA SHEET

1. TRANSACTION CODE SA 6244 Amendment Number
 A = Add
 C = Change
 D = Delete

DOCUMENT CODE **3**

2. COUNTRY/ENTITY Worldwide

3. PROJECT NUMBER 936-3044

4. BUREAU/OFFICE ST/POP 36

5. PROJECT TITLE (maximum 40 characters)
(CONRAD) Contraceptive Research and Development

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)
 MM DD YY
09 30 96

7. ESTIMATED DATE OF OBLIGATION (Under 'B' below, enter 1, 2, 3, or 4)
 A. Initial FY 86 B. Quarter 3 C. Final FY 95*

8. COSTS (\$000 OR EQUIVALENT \$1 =)

A. FUNDING SOURCE	FIRST FY			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	4,750		4,750		80,680	80,680
(Grant)	(4,750)	()	(4,750)	()	(80,680)	(80,680)
(Loan)	()	()	()	()	()	()
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
TOTALS	4,750		4,750		80,680	80,680

9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1)	431	430				31,760		31,760	
(2)									
(3)									
(4)									
TOTALS						31,760		31,760	

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)

11. SECONDARY PURPOSE CODE

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code

B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

To develop improved methods of family planning for use in developing countries.

14. SCHEDULED EVALUATIONS

Interim MM YY MM YY Final MM YY
06 88 06 90 06 95

15. SOURCE/ORIGIN OF GOODS AND SERVICES
 000 941 Local Other (Specify) 935

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a _____ page PP Amendment.)

*LOP cost over the ten year period FY86-95 is \$80,680,000.
 Authorization of S&T funding of \$31,760,000 is requested for the first five years of this project.

17. APPROVED BY

Signature Steven W. Sinding

Title Director, S&T/POP

Date Signed MM DD YY 11/16/85

DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION
 MM DD YY

PROJECT AUTHORIZATION

Country: Interregional

Project: Contraceptive Research
and Development

Project No.: 936-3044

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the centrally funded project, Contraceptive Research and Development, involving planned obligations not to exceed \$31,760,000 in grant funds over a five-year period from the date of authorization, subject to the availability of funds in accordance with the A.I.D. OYB/allotment process, to help in financing foreign exchange and local currency costs for the project.

2. The purpose of the project is to develop improved methods of family planning for use in developing countries.

3. The agreement which may be negotiated and executed by the officer to whom such authority is delegated in accordance with A.I.D. regulations and Delegations of Authority shall be subject to the following terms and conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

4. Source and Origin of Commodities, Nationality of Services

a. Commodities financed by A.I.D. under the project shall have their source and origin in the cooperating country* or the United States, except as A.I.D. may otherwise agree in writing. Except for ocean shipping, the suppliers of commodities or services shall have the cooperating country or the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

b. The aggregate cost of all goods and services procured under each subagreement in a cooperating country may not exceed \$750,000.

*Each country where research, training, technical, or other assistance takes place under the project shall be deemed to be a cooperating country for the purpose of permitting local cost financing of goods and services for the activity being conducted in such country. Such activities may be undertaken in any country included in A.I.D. geographic code 935.

c. Ocean shipping financed by A.I.D. under the project shall, except as A.I.D. may otherwise agree in writing, be financed only on flag vessels of the United States.

M. Peter McPherson

M. Peter McPherson
Agency Administrator

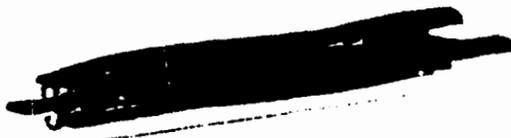
Jan 13 1986

Date

Clearances:

MS S&T/POP/R, JDS Shelton *JDS*
MS S&T/POP, SWSinding *SWS*
 S&T/PO, GEaton *KA*
 S&T, NCBrady *NCB*
 GC/CP, STisa *STI*
MS GC/CP, HFry *HFR*
 AA/PPC, RADERham *RAD*

Drafted by: ST/POP/R:JM Spieler *JMS*:jms:12/4/85:x59686:1975Z

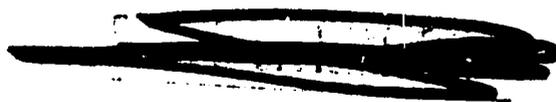


The CONRAD Project is the follow-on of the Program for Applied Research on Fertility Regulation (PARFR), Northwestern University. The PARFR Project was established by A.I.D. in 1972 to solicit, review, fund and monitor applied research projects in the field of fertility regulation, and to organize and convene meetings and workshops and disseminate technical publications. The Program is administered by a small staff and was designed primarily as a "pass-through" mechanism which subcontracts for all of its research and development activities.

Over the past few years scientific advancements have been made in highly specialized areas such as immunology, molecular biology, bioengineering, delivery systems and polymer chemistry. Today, an organization supporting contraceptive research and development must be fully conversant in the application of these new biotechnologies in order to progress as rapidly as possible. In addition, the process of obtaining drug regulatory agency (FDA) approval at various stages of development has become increasingly more complicated and requires much more technical knowledge and sheer volume of work than previously. The current technological sophistication of the total field, and the complicated series of steps required to develop new products, now requires an in-house multi-disciplinary staff, including basic laboratory and clinical scientists, if it is to be both effective and efficient in nurturing new leads from the basic applied stage through the initial clinical testing phases.

Accordingly, the needs of the field now require a level of technical oversight and in-house capability difficult to incorporate in an exclusive "pass-through" model. For this reason, the CONRAD Project will improve upon the current PARFR mechanism; while maintaining a large amount of "pass-through" support of subprojects conducted by collaborating investigators, the new Project will also support a critical mass of scientific personnel with technical expertise in a wide range of disciplines. Moreover, the cooperating agency (C.A.) selected will have significant responsibility for conducting in-house animal, laboratory and clinical research.

CONRAD will deal primarily with research and development activities beginning with targeted basic research studies in animals through the first two phases (I and II) of clinical trials, i.e., pharmacodynamics, pharmacokinetics and preliminary safety and efficacy studies in relatively small numbers of volunteers. Although the Project can pursue any avenue of applied research directed towards contraceptive development consistent with Foreign Assistance regulations, priority will be accorded to methods that:



- provide long-acting contraception
- inhibit ovulation or the maturation of ova or sperm
- interrupt the transport of ova and/or sperm
- interfere with the process of fertilization.

As the field develops and new leads are identified, the project will be flexible enough to support, on a quick response basis, research on a wide variety of approaches.

The C.A. will also be responsible for taking a position of technical leadership in the field through convening scientific meetings, conferences, workshops, seminars, etc., and by widely disseminating technical publications. The C.A. will take some responsibility to ensure that research supported and conducted by other agencies and organizations is as well coordinated as possible to avoid unnecessary duplication of effort. In addition, consideration will be given to supporting the participation of developing country scientists in U.S.-based projects either as part of the budget of a subproject or under a fellowship or research training grant.

It is anticipated that a C.A. will be selected competitively for the initial five-year award. However, since it is A.I.D.'s intent to build a long-term institutional capability to conduct contraceptive R&D, successful performance by the recipient may result in a decision to make a second five-year award without consideration of other sources. The institution selected must share A.I.D.'s mission-oriented research philosophy; be willing to collaborate with A.I.D. in actively seeking out new leads and identifying, developing, reviewing, monitoring, implementing and evaluating project activities; possess a technical and administrative staff, and the facilities required, to undertake the workscope; and have experience in carrying out early applied contraceptive R&D.

An expert Technical Advisory Committee (TAC) will be established to provide advice to the C.A. and A.I.D. It will assist in establishing priorities, developing new projects, reviewing proposals, and evaluating program activities. Primary technical and administrative responsibility will rest with the Research Division, Office of Population (ST/POP/R).

Agency Policy: The Project will be implemented in accordance with relevant Agency policies including those on abortion, natural family planning, voluntary sterilization and human subjects research.

Justification to Congress: An advice of program change has been drafted and is in process.

Clearances Obtained: A ten-year Project Paper (FY 86 - FY 95) was prepared, reviewed and strongly endorsed at all levels of the Agency. However, we are only requesting authorization for the first five years at this time. This five-year authorization (a) reflects no commitment on your part to go beyond five years and (b) will encompass activities which can be accomplished in five years. The Population Sector Council reviewed the Project Paper on December 4, 1985 and unanimously recommended approval. Minutes of that review are attached. The one suggestion of the Council, i.e., to indicate that funds were available to provide research training fellowships for LDC scientists, was incorporated in the Project.

Certification of the Procurement Plan: Certification that the procurement plan for this Project Paper was developed with full consideration of maximum involvement by minority and women-owned firms, historically Black colleges and universities and minority controlled PVOs in the provision of goods and services, and that the Project is not appropriate for minority or Gray amendment contracting is attached to the Project as Annex 1.

Recommendation: That you sign the attached Project Authorization.

Attachments:

1. Project Authorization
2. Project Paper (936-3044)
3. Minutes of the Population Sector Council Meeting, December 4, 1985

Clearances:

ST/POP/R, JDShelton
ST/POP, SWSinding
ST/PO, GEaton
GC, HFry
PPC/PDPR, ARosenberg

Drafted by: ST/POP/R:JMSpiele: jms:12/4/85:x59686:1975Z

Contraceptive Research and Development
(CONRAD)

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A. SUMMARY

The Bureau for Science and Technology proposes a new Contraceptive Research and Development (CONRAD) Project, 936-3044, at an estimated cost of \$80.68 million over a ten-year period. Initial authorization will be requested for the first five years of the Project at an estimated cost of \$31.76 million. This project is designed to improve family planning technology available for use in the less developed countries (LDCs).

A major goal of the A.I.D. population assistance program is to enhance the freedom of individuals in the LDCs to choose voluntarily the number and spacing of their children. One clear way to improve A.I.D.'s support to family planning programs is to develop and introduce better, safer, more varied, and more acceptable methods of family planning. The availability of improved technology should greatly enhance the individual's options and thus increase the prevalence of contraceptive use, particularly in the LDCs.

Present family planning methods have severe limitations and a variety of methods, better than those available today, is urgently needed. Long a significant component of A.I.D.'s population program, the development of new and improved family planning methods has recently been recognized as a particular Agency priority. This included the White House instructions accompanying the Policy Statement prepared for the International Conference on Population in Mexico City, August 1984:

"There should be higher international priority for biomedical research into safer and better methods of fertility regulation, especially natural family planning"

Numerous other similar statements supporting the need to increase contraceptive development research have been made at international conferences on family planning supported by governments, inter-governmental agencies and private organizations.

Consistent with the White House policy and in recognition of the worldwide expressed need to improve the availability of a wide range of family planning methods, A.I.D. support for such research has increased markedly in recent years.

This new CONRAD Project has been developed in order to contribute towards the worthy public purpose of identifying, supporting, conducting and monitoring high quality and timely research activities worldwide that will lead to the development of improved and totally new methods of fertility regulation. Under this Project, new institutions and investigators will be identified for collaboration. Also, new research leads will be developed which should increase our knowledge of the reproductive processes of men and women and lead to the development of novel, safe, acceptable and effective contraceptive methods. While maintaining a large amount of "pass-through" support of subprojects conducted by collaborating investigators, a significant amount of in-house animal, laboratory and clinical research will be conducted by the Cooperating Agency (C.A.) selected. The Project will have a central staff with expertise in a wide range of disciplines. The mechanism being proposed should maximize the likelihood of developing new methods as it incorporates the most successful aspects of several models in the field.

The Project will accord special attention to the early stages of contraceptive development research (applied basic or targeted fundamental research) and clinical research. The C.A., competitively selected, must have technical expertise in the areas covered under this Project, and the capability to manage and implement a comprehensive research program in order to:

- maximize the efficiency and effectiveness of the Project,
- ensure that important linkages between Project activities are developed and maintained, and
- ensure that supported research and development is coordinated with other organizations funding and conducting similar activities.

A Technical Advisory Committee (TAC) will be established to provide advice to the C.A. and A.I.D. The TAC will assist in:

- establishing priorities
- developing new projects
- reviewing proposals
- evaluating program activities

B. BACKGROUND

A.I.D. is committed to helping developing countries meet basic human needs and overcome problems associated with hunger, illiteracy, disease and infant mortality. In the economic history of nations, population growth has been a major determinant of economic growth. Where rapid population increases outstrip economic growth, governments are faced with enormous burdens to provide basic services such as health and education. Rapid population growth rates compound the problems of hunger, natural resource degradation, illiteracy and disease. For these reasons, family planning programs are an essential element of the U.S. development assistance strategy. A.I.D.'s support to voluntary family planning efforts began more than 20 years ago. The ability to determine freely the number and spacing of one's children allows the individual greater freedom to take advantage of opportunities for the abatement of hunger, the eradication of illiteracy and disease and, eventually, for improved employment opportunities and family income.

An area of special importance to A.I.D. is improving family planning technology through research and development (R&D). The development of new and improved family planning methods is one of the Agency's five priority research areas. Since 1982, A.I.D. funding for biomedical research on family planning and contraceptive development has almost doubled. A.I.D. support has already led to safer and more effective voluntary sterilization procedures, the use of lower-dose oral contraceptives, and new and improved vaginal contraceptives and IUDs. Funding is being increased to accelerate the development of new technologies which should be available for use in the near term, between 1988-1992, and in the long term, by the year 2000. In addition to developing new and improved methods, the Agency's biomedical research program supports clinical testing to assess acceptability, safety and effectiveness of contraceptive technologies in developing country settings, and the transfer of such technologies to the LDCs.

In accordance with the A.I.D. principles of voluntarism and informed choice, and recognizing that no single method will ever satisfy the needs of all family planning users worldwide, A.I.D.'s research program is directed toward wide availability and accessibility of multiple methods of contraception. The Agency's research priorities for improving existing methods and developing entirely new methods include:

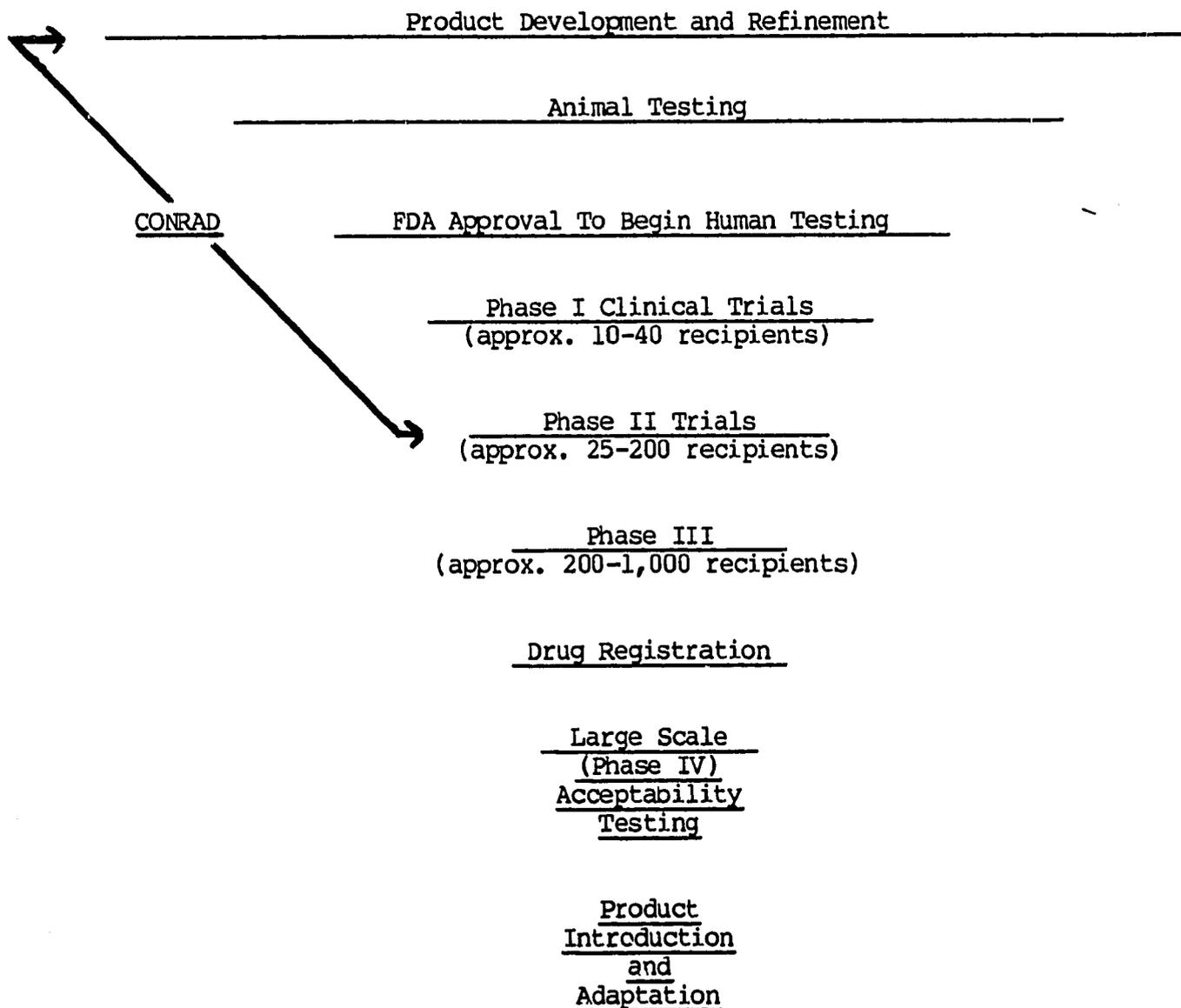
- Oral Contraceptives
- IUD's
- Male and Female Non-Surgical and/or Reversible Sterilization
- Barrier/Vaginal Methods
- Long-acting Implants for Women and Men
- Long-acting Injectables for Women and Men
- Natural Family Planning and Methods to Predict and Detect Ovulation
- Contraceptive Vaccines
- Various Other Pharmacological Methods for Men and Women

Only a handful of public sector agencies are involved in contraceptive development. The primary Agencies are the World Health Organization Special Programme of Research in Human Reproduction (HRP); the Population Council, including its International Committee for Contraceptive Research (ICCR); the Contraceptive Development Branch (CDB) of the National Institutes of Health (NIH), Center for Population Research; Family Health International (FHI); the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT); and the Program for Applied Research on Fertility Regulation (PARFR) of Northwestern University. Each of these programs has areas of emphasis, but only one (the Population Council) even approaches a comprehensive attempt to develop contraceptives including a significant amount of in-house, hands-on research. Recently, this program has been most successful in developing new methods. PIACT focuses on product introduction and FHI focuses on activities usually beginning with Phase III clinical trials. The CDB of NIH addresses family planning needs of the U.S. and primarily provides contract support to U.S. institutions in specific areas. HRP is quite comprehensive, but does not carry out in-house research. Figure 1 provides a simplified diagram of the steps in the process of developing contraceptives.

The PARFR project was established by A.I.D. in 1972. It was created to solicit, review, fund and monitor applied research projects in the field of fertility regulation, specifically the development of new or improved contraceptives. The Program is administered by a small staff composed primarily of a Director of Technical Assistance, a Head of Research Project Development, a Director of Administration and three to four support staff. Currently, PARFR is primarily a "pass-through" mechanism which subcontracts for all of its R&D activities. However, the in-house staff take direct responsibility for organizing and convening meetings, workshops and seminars; publishing the proceedings of the workshops and a research review monograph series; and disseminating information to the scientific community worldwide. While the CONRAD Project will include these essential elements of the PARFR Project, it will have additional elements allowing it to address better the current complexity of the contraceptive development field. The CONRAD model will provide an optimal critical mass of scientific personnel and a significant amount of "in-house" research.

FIGURE 1

Simplified Schematic* on Contraceptive Development



*While listed sequentially, in reality these various activities often overlap or occur in parallel and may be reinitiated several times and at any time.

Experience has shown that contraceptive development clearly benefits from divergent views and approaches, and from a plurality of organizations working in the field. Indeed, many believe that a major impediment to the development of new contraceptives is the relative paucity of organizations and investigators committed to this area. The CONRAD Project will occupy the same high priority "ecological niche" as its predecessor, but its depth, complexity and overall effectiveness will be enhanced. We believe that through this restructuring, the CONRAD Project will include the best aspects of other models in the field, thus maximizing the likelihood of developing new contraceptives. Unnecessary overlap with other contraceptive development programs will be prevented through close collaboration and joint programming wherever possible.

A full description of the complex relations and interactions among the agencies supporting and conducting contraceptive research is well beyond the scope of this project paper. However, the current system actually promotes a high degree of both collaboration and healthy competition. This was well documented in a recent study carried out by the Alan Guttmacher Institute which inventoried dozens of ongoing collaborative research projects. In the case of FHI, its relationship to CONRAD will be reasonably straight forward: CONRAD will focus on "early" research through Phase I and II clinical trials, while FHI, for the most part, will focus on later stages of product development and testing. In the case of other agencies that carry out early phase research, such as HRP, ICCR and CDB, CONRAD will seek to coordinate and collaborate to the maximum extent possible and to avoid unnecessary replication of the work of these agencies.

C. PROJECT DESCRIPTION

1. GOAL - To enhance the freedom of individuals in LDCs to choose voluntarily the number and spacing of their children.

2. PURPOSE - To develop improved methods of family planning for use in developing countries.

3. RATIONALE - During the earlier years of the Agency's support for contraceptive development research, an organization (PARFR) which solicited, reviewed, funded and managed applied research projects was appropriate to provide the type of support that was necessary to begin developing new contraceptive leads. However, over the past few years scientific advancements have been made in highly specialized areas such as immunology, molecular biology, bioengineering, delivery systems and polymer chemistry. Today, an organization supporting contraceptive research and development must be fully conversant in the application of these new biotechnologies in order to progress as rapidly as possible. In addition, the process of obtaining drug regulatory agency (FDA) approval at various stages of development has become increasingly more complicated and requires much more technical knowledge and sheer volume of work than previously. The current technological sophistication of the total field, and the complicated series of steps required to develop new products, now requires an in-house multi-disciplinary staff, including basic laboratory and clinical scientists, if it is to be both effective and efficient. Furthermore, it can be anticipated that, in the

future, many new leads will require a technologically diverse staff that can nurture a project from the basic applied stage through the clinical testing phases.

The scientific evolution over the past decade requires a level of technical oversight and in-house capability difficult to incorporate in a exclusive pass-through model. The CONRAD Project will improve the current pass-through mechanism. While maintaining a large amount of "pass-through" support of subprojects conducted by collaborating investigators, the new Project will also support a much larger central staff with technical expertise in a wide range of disciplines. Moreover, the C.A. will have significant responsibility for conducting in-house animal, laboratory and clinical research. The Project staff will continue to take responsibility for organizing and convening scientific meetings and disseminating technical information through publications.

CONRAD will be primarily directed at developing several priority leads. Still, it should be flexible enough to respond to rapidly appearing opportunities. The Project must have a critical mass of disciplines necessary to ensure that essential steps in contraceptive research and development are addressed in a competent technical manner and that individual projects fit within a strategic R&D plan developed for each potential product. It is anticipated that approximately one-third of the funds available for R&D will be obligated for in-house projects while two-thirds will be used to support activities through subcontracts with collaborating scientists and institutions. The determination of the R&D elements of the workscope that will be conducted in-house versus those activities that will be subcontracted externally will depend upon the capabilities of the C.A. and the types of subprojects (see Section D.2).

The field of contraceptive development has reached the point where several leads are, or will be, available for clinical testing, e.g., new injectable and implantable contraceptives, new methods of sterilization. However, increasing demands placed on the field by the regulatory agencies have tremendously increased the amount of work, time and money required to develop interesting leads into new products. Nevertheless, highest priority will be accorded under this Project to moving leads through the necessary steps required to conduct Phase I and II clinical trials.

In the 1960s pharmaceutical companies were devoting a great deal of resources to the development of contraceptive methods. However, over the past several years many U.S.-based pharmaceutical companies have dropped their contraceptive R&D programs. This action is due to a variety of reasons, including the time and costs involved in developing new contraceptives, a less favorable ratio of cost to profit than in other fields, the ever-increasing requirements of the drug regulatory authorities, and problems related to product liability. Nevertheless, owing to the wealth of knowledge and experience in the pharmaceutical companies, the CONRAD Project will attempt to work closely with the private sector to provide a mechanism for cost sharing. It should be noted that the pharmaceutical companies have experience collaborating with public sector organizations and funding agencies.

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4. TYPE OF INSTITUTION NEEDED (see also Section D.2)

It is anticipated that a C.A. will be selected competitively for the initial five-year award to support the worthy public purpose of working on the development of a wide range of safe, effective and acceptable methods of family planning. However, since it is A.I.D.'s intent to build a long-term institutional capability to conduct contraceptive R&D, successful performance by the recipient may result in a decision to make the second five-year award without consideration of other sources. The institution selected must:

- share A.I.D.'s mission-oriented research philosophy;
- be willing to collaborate with A.I.D. in actively seeking out new leads and identifying, developing, reviewing, monitoring, implementing and evaluating project activities;
- possess a technical and administrative staff, and the facilities required, to undertake the workscope (see Section D. 2.1 and 2.2); and
- have experience in carrying out early applied contraceptive R&D.

The special needs of developing countries, and the rapidly evolving nature of this complex multi-disciplinary field, require that the C.A. and A.I.D. work together closely in determining Project priorities and allocations.

5. ACTIVITIES

The CONRAD Project has been developed in order to identify, develop, support, and monitor high quality and timely research activities worldwide that will lead to the development of improved and totally new methods of fertility regulation. New institutions and investigators will be sought to collaborate with, as will new research initiatives which can contribute to our knowledge of the reproductive processes of men and women leading to the development of novel safe, acceptable and effective contraceptive methods suitable for use in developing countries. While maintaining the highest level of technical competence, emphasis will be placed on involving developing country scientists in the work of the Project, particularly in early clinical testing and through fellowships which will permit LDC investigators to work on subprojects conducted in the U.S. Nevertheless, it is anticipated that the majority of work will take place in developed countries.

Inherent in the purpose of the project is the need to bridge the gap between the numerous disciplines required to develop specific new contraceptive products, the gap between potential collaborators in the public and private sectors, and the gap between research results available to scientific investigators and family planning administrators and service providers in the developing countries. Particularly important is the need for the Project staff to work closely with pharmaceutical companies and other firms to capitalize on the special expertise and capability of the private sector.

The C.A. will draw upon an expert Technical Advisory Committee (TAC) which will provide assistance in establishing program priorities; identifying and developing new activities and subprojects; reviewing proposals; and implementing, monitoring and evaluating the total program. The C.A. will also maintain a roster of expert consultants, investigators and institutions capable of providing technical assistance and undertaking all types of biomedical research and development. These consultants and investigators will

have expertise in such specialized areas as reproductive biology, endocrinology, gynecology, urology, internal medicine, immunology, epidemiology, clinical trials, clinical laboratory methods, product development, delivery systems, bioengineering, physical chemistry, animal science, pharmacology, toxicology, etc. It should be emphasized the TAC and consultants will represent human resources to the project staff and A.I.D., will act in an advisory capacity, and will represent a peer review mechanism.

5.1 RESEARCH

One of the ways of meeting the challenge of making family planning more widely available and acceptable is through the improvement of current methods of fertility regulation and the development of new methods. The side-effects of many of the current methods, or their inconvenience of use, are responsible largely for failure to adopt family planning, or failure to continue using a method. Some types of methods are entirely lacking, such as systemic contraceptives for men, birth control vaccines and non-surgical, reversible sterilization for men and women. Multi-disciplinary activities involving basic reproductive physiology; chemistry; bioengineering; animal studies and pre-clinical toxicology; product development, formulation and reformulation; clinical trials; product introduction, packaging and registration are required to develop new contraceptives. This project will deal primarily with research and development activities beginning with targeted basic research studies in animals through the first two phases (I and II) of clinical trials, i.e., pharmacodynamics, pharmacokinetics and preliminary safety and efficacy studies in relatively small numbers of volunteers once FDA approval, in the form of an investigational new drug (IND) or investigational new device exemption (IDE), is obtained (see Figure 1). Upon completion of Phase I or Phase II clinical trials, the technology being investigated will generally be passed on to another A.I.D.-supported Cooperating Agency which will take responsibility for completing the development of the method, usually with the support of the private sector.

While all areas of R&D of new contraceptives could benefit from increased funds, in general, the area most lacking in support, and which will receive some emphasis under this project, is so-called mission-oriented or fundamental applied research. This includes research that falls somewhere between truly basic research conducted simply to understand reproductive science and processes, and more advanced applied research with relatively well-understood technology. Mission-oriented research has a specific goal in mind (such as the development of a contraceptive vaccine against the zona pellucida), but there are important gaps in knowledge and a substantial amount of applied basic research needs to be undertaken.

Although the Project can pursue any avenue of applied research directed towards contraceptive R&D consistent with Foreign Assistance regulations, priority will be accorded to methods that:

- provide long-acting contraception (30, 90, 180 and 360 days)
 - inhibit ovulation or the maturation of ova or sperm at the central or local level
 - interrupt the transport of ova or sperm and prevent gamete union
- 17

- interfere with the process of fertilization

Examples of current leads that should be pursued under this project include:

- Injectable preparations (microspheres or microcapsules) that inhibit ovulation and/or that render cervical mucus impenetrable by sperm
- Biodegradable or non-biodegradable implants of contraceptive steroids
- Methods of birth spacing that are suitable for use in lactating women
- Contraceptive vaccines using ovum, sperm or hormonal antigens for women and men
- Tubal or vas plugs that provide for reversible contraception
- Adhesives, chemicals or other materials that can be delivered "blindly" (non-surgically) either transcervically or transcutaneously for female or male sterilization, respectively
- Locally applied chemical preparations for vaginal contraception that immobilize sperm and/or interfere with cervical mucus
- New self-inserted barrier methods
- Non-steroidal systemic antifertility agents for women and men
- Improved intrauterine or intracervical contraceptive devices
- Simple, do-it-yourself methods of predicting and detecting ovulation and identifying the fertile period

In addition to this illustrative list of leads, as the field develops and new leads are identified, the project will be flexible enough to support, on a quick response basis, research on other approaches.

5.2 TECHNICAL LEADERSHIP AND INFORMATION DISSEMINATION

The C.A. will be responsible for taking a position of technical leadership in the field through convening scientific meetings, conferences, workshops, seminars, etc., and by widely disseminating technical publications. The C.A. will take some responsibility to ensure that research supported and conducted by other agencies and organizations is as well coordinated as possible to avoid unnecessary duplication of effort. In addition, consideration will be given to supporting the participation of developing country scientists in U.S.-based projects either as part of the budget of a subproject or under a fellowship or research training grant.

a. International and Regional Workshops, Seminars, Conferences and Meetings

The C.A. will be responsible for organizing and convening an annual international workshop which will bring together leading international scientists and clinicians from developed and developing countries to present their work and to exchange ideas on research and developments related to

specific topics of fertility regulation. These workshops can be held in the U.S., in other developed countries, and in LDCs. The C.A. will also be responsible for organizing regional seminars, in LDCs, on topics of specific concern to the region and A.I.D.

As part of subproject development the Project will also convene meetings of collaborating investigators participating in specific studies. Furthermore, funds can be provided to organize seminars and plenary sessions in association with national and international conferences and congresses and to support the participation of collaborating investigators, specifically from LDCs, to attend pertinent conferences and fora to present results of Project-supported research.

b. Publications

The C.A. will be responsible for organizing the publication of the proceedings of workshops and seminars, as appropriate; for commissioning or directly preparing reviews of findings of applied contraceptive research on fertility regulation; for publishing a semi-annual or quarterly bulletin/monograph on timely subjects related to contraceptive R&D; and for widely disseminating these publications. As appropriate, Communications Review Board approvals will be obtained.

D. IMPLEMENTATION

1. A.I.D. MANAGEMENT

Primary technical and administrative responsibility will rest with the Research Division, Office of Population (ST/POP/R). The A.I.D. cognizant technical officer (CTO) will provide the C.A. with overall technical guidance and ensure that project implementation is consistent with the design set forth in this Project Paper. The CTO will undertake appropriate coordination with other offices in the Agency such as the Regional Bureaus and A.I.D. Missions. When appropriate, the CTO will arrange for Mission clearances for proposed activities and travel.

Consistent with the "substantial involvement" concepts underlying a cooperative agreement, the CTO will exercise a variety of functions including:

1. Collaborative involvement in the development of an annual strategy (workplan), and all modifications of the strategy, which describes the specific activities to be carried out under the agreement.
2. Collaborative involvement in selecting TAC members, establishing priorities and developing and modifying the scientific research agenda, and the meetings and information dissemination agenda.
3. Approval of all activities carried out under this agreement including strategies, protocols, subcontracts, information dissemination, consultancies, and international travel.
4. As appropriate, involvement in analysis and publication of findings.
5. Participation in site visits, TAC meetings and evaluations to review program progress and future strategy.

2. COOPERATING AGENCY (C.A.)

It is anticipated that the technical resources of a C.A. will be obtained competitively in accordance with A.I.D. regulations to carry out project activities. The nature and requirements of this technical project make it highly unlikely that minority and women-owned firms, historically Black colleges and universities and minority controlled PVOs would be the recipient of the prime agreement to conduct and monitor state-of-the-art contraceptive R&D (see Annex 1, Certification of the Procurement Plan). Nevertheless, under subprojects, participation of such organizations will be encouraged to the maximum extent.

The C.A. will carry out needs assessments; advise on program priorities; coordinate activities; and conduct, oversee and monitor this highly technical program of research and development and information dissemination. It is estimated that the C.A. will carry out directly about one-third of technical activities and subcontract for the remainder. The C.A. must have in-house expertise and demonstrated competence in research and experience in product development, developing project protocols, organizing and conducting clinical trials, and organizing international workshops and seminars. The C.A. must be able to present a staff and roster of consultants and investigators/institutions in the U.S. and abroad who possess technical expertise related to the above-mentioned areas.

Specifically, the C.A. will be responsible for activities such as, but not limited to:

- Organizing and convening a TAC
 - Undertaking "in-house" laboratory and clinical research aimed at developing and/or assessing new contraceptive drugs, devices and procedures
 - Actively seeking out, identifying and developing projects or soliciting proposals in priority areas
 - Providing an "open grant" mechanism (review and funding of unsolicited subprojects in all areas related to the workscope) to support ad hoc projects and feasibility studies
 - Managing research on the development of contraceptive methods
 - Providing technical assistance and encouragement to LDC investigators and institutions to prepare proposals and to have the facilities required to participate in single- or multi-centered studies
 - Responding quickly to the needs and directions of A.I.D.
 - Fostering a spirit of collaboration and coordination between and among private and public sector organizations conducting or supporting contraceptive R&D, and between U.S.-based and foreign investigators and institutions conducting research in this area
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- Processing proposals through appropriate review mechanisms, including institutional review boards, and prepare, negotiate and process subcontracts
- Administering and monitoring funded activities, and organizing and participating in site visits and evaluations as appropriate
- Serving as an intermediary between potential investigators, subcontractors, the TAC and A.I.D.
- Developing and maintaining a roster of technical experts and consultants
- Developing and maintaining a roster of worldwide investigators who are capable and ready to undertake specific projects as required
- Developing a network of worldwide centers capable and ready to participate in single- or multi-centered clinical trials
- Developing a network of specialized laboratories capable and ready to undertake animal testing and pre-clinical toxicology required to obtain FDA and other drug regulatory approvals
- Keeping abreast of advances in the field of reproduction and contraceptive R&D, and of current FDA requirements for obtaining INDs and IDEs
- Keeping abreast of research and development activities being undertaken by the private sector (e.g., pharmaceutical companies) worldwide
- Organizing and convening technical meetings, conferences, workshops and seminars at national, regional and international levels
- Preparing and editing technical publications
- Developing and maintaining a mailing list of scientists worldwide and disseminating technical information widely

The determination of the R&D elements of the workscope that will be conducted in-house versus those activities that will be supported externally will depend upon the capabilities of the C.A. and the nature of the subprojects. For example, by necessity a multicenter Phase I or Phase II clinical trial will involve subcontracting with other institutions/investigators. However, some organizations may have the facilities available within the C.A.'s institution to conduct pre-clinical animal toxicology or teratology studies, while other potential C.A.s would have to rely on subcontracting for the conduct of all or part of such work. Furthermore, a potential C.A. may have expertise in a some specific areas, such as male reproduction, spermicides, or delivery systems but not in other areas, e.g., non-surgical sterilization or immunocontraception. In such cases, the C.A. would propose which areas of research and which types of projects require subcontracting with external institutions. Moreover, since the Project will have an explicit "open grant" component, "outside" proposals submitted for review (by the Project staff and/or the TAC) and recommended for support will be funded under a subcontract. The application process for competitively selecting a C.A. will

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involve the submission of necessary information to enable the Evaluation Panel to determine which components of the R&D work would be conducted within house versus those that would be conducted through subcontracts.

With regard to the competitive selection process, we anticipate that the applicants will also be requested to submit information that will enable the Panel to assess their understanding of the current state-of-the-art in contraceptive R&D. To help accomplish this important determination, the applicants will be asked to review the lists of current leads identified throughout this Project Paper, to add to the list, and then to rank the leads in priority order including the following criteria:

- projected acceptability to family planning users in LDCs
- perceived usefulness to family planning programs in LDCs
- probability of success (feasibility)
- timeframe (number of years) until product introduction
- total estimated cost from present to product introduction
- degree of support provided to lead by other agencies

2.1 COOPERATING AGENCY STAFF

It is anticipated that the Project will support a senior technical staff of about five full-time equivalent professionals in areas related to clinical gynecology, reproductive physiology, pharmacology/toxicology, immunology, bioengineering, etc.; a couple of mid-level project officers; and a senior administrator with four support staff and a part-time writer/editor.

Illustrative staff requirements by grade and time on Project are as follows:

<u>Professional</u>	<u>Approximate GS Level</u>	<u>Full-Time Equivalents</u>
<u>Full-time</u>		
Senior Project Director	15	100%, 60 pm
Senior Biomedical Scientist (Reproductive Physiologist)	14-15	100%, 60 pm
Senior Clinical Scientist (Obstetrician-Gynecologist)	14-15	100%, 60 pm
Senior Product Development Specialist	14-15	100%, 60 pm
Project Administrator	13-14	100%, 60 pm
Mid-level Technical Assistants Biologists/Project Officers	9-11	200%, 120 pm
<u>Part-time</u>		
Senior Principal Investigator	15	10%, 6 pm
Bioengineer	14-15	25%, 15 pm
Immunologist/Reproductive Immunologist	14-15	20%, 12 pm
Pharmacologist/Toxicologist	14-15	20%, 12 pm
Social Scientist	13-14	25%, 15 pm
Writer/Editor	12-13	25%, 15 pm

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Support Staff

Full-time

Bi-/Tri-lingual Secretary	6-7	100%, 60 pm
Secretary	5-6	200%, 60 pm
Bookkeeper	6-7	100%, 60 pm

pm = person months

2.2 FACILITIES

The C.A. must have the facilities necessary to carry out the program described, e.g., access to computer facilities, biomedical research laboratories, family planning clinics, capability to conduct Phase I and II clinical trials, communications and mailing systems, etc. Project funds will not be available for renovation of facilities, construction, etc.

3. TECHNICAL ADVISORY COMMITTEE (TAC)

A TAC will be established by the C.A. with the recommendations and concurrence of the CTO. The C.A. will identify suitable experts who will be invited to join the TAC. The TAC will advise the C.A. and the CTO, assist the C.A. in (a) developing projects (through their knowledge of, and contacts in their field of expertise as it relates to the activities of the project); (b) reviewing proposals at meetings of the TAC and recommending specific amendments/modifications, where appropriate (based on criteria approved by the CTO); (c) monitoring funded projects (by reviewing technical progress reports primarily at TAC meetings); and (d) providing general technical assistance to the C.A. and CTO as requested. The TAC will act in an advisory capacity and will represent, amongst other things, a peer-review mechanism.

The TAC will have from 10-12 members drawn from around the U.S. (but not limited to the U.S.) and meet from two to four times per year. The TAC members will have technical expertise in areas such as:

- Clinical Obstetrics and Gynecology
- Reproductive Physiology/Endocrinology
- Pharmacology
- Immunology
- Toxicology
- Bioengineering
- Product Development
- Epidemiology
- Family Planning Services
- Social Science/Acceptability Research

The criteria for selecting TAC members will be developed by the C.A. and the CTO. The TAC and C.A. staff will recommend additional ad hoc members or reviewers when other special expertise is required. The C.A. will provide administrative support to the TAC. Project priorities will be translated into project activities by the C.A. in collaboration with A.I.D./CTO and TAC and

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incorporated in the annual strategy document (workplan). The tenure of TAC members, and the frame of reference and modus operandi of the TAC, will be established by the C.A. with the concurrence of the CTO.

4. COORDINATION AND IMPLEMENTATION OF PROJECT ACTIVITIES

4.1 COORDINATION

The C.A. will act as one of the Agency's primary technical resources for applied research on the improvement of existing fertility regulating methods and the development of new methods. It will be expected to establish good working relations with all appropriate A.I.D. Bureaus, Missions, and other Contractors and Grantees working in similar areas. The C.A. will be responsible for coordinating and collaborating with other agencies and organizations supporting and conducting contraceptive R&D worldwide to ensure that it does not unnecessarily duplicate or repeat the work of other organizations.

4.2 DEVELOPMENT, MANAGEMENT AND IMPLEMENTATION

The steps involved in developing, managing and implementing subprojects and other activities include assessing current knowledge and needs; identifying capable collaborators, institutions, and consultants; obtaining necessary clearances and approvals; designing, funding, monitoring and evaluating projects; and analyzing, writing up and disseminating results. Meetings drawing together experts in relevant disciplines may be required to provide direction for specific research.

5. BUDGET

The total life of project funding will be \$80.68 million over 10 years. The budget for the first five years is \$31.76 million, with the following yearly breakdown: FY86 - \$4.75 million; FY87 - \$5.772 million; FY88 - \$7.016 million; FY89 - \$6.952 million; and FY90 - \$7.27 million.

5.1 Illustrative Budget	(\$000)					Total 10 Years
	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>	<u>Year 4</u>	<u>Year 5</u>	
Salaries and Benefits	1,000	1,100	1,200	1,300	1,400	15,500
TAC and Consultants	100	120	140	140	145	1,610
Travel and Per Diem	200	240	280	280	290	3,215
Supplies and Equipment	150	165	180	200	220	2,440
Workshops, Seminars and Publications/Printing)	200	240	280	280	280	3,100
In-house Research	500	600	800	880	900	10,000
Subagreements	1,450	1,935	2,320	2,200	2,285	25,335
Overhead (20% overall)	<u>1,150</u>	<u>1,372</u>	<u>1,816</u>	<u>1,672</u>	<u>1,750</u>	<u>19,400</u>
Grand Total for Project	4,750	5,772	7,016	6,952	7,270	80,680

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6. REPORTS

The C.A. shall submit reports as follows:

1. Two reports will be submitted annually consisting of interim activity reports (submitted six months after the Project commences and then at 12-month intervals) and annual progress reports (submitted 12 months after the project commences and at 12-month intervals). All reports shall be submitted to the A.I.D. CTO in six copies covering ongoing and completed activities as well as plans for the next six months. The reports should include, but not be limited to, a description of activities, summary of results and accomplishments and problems in the areas of program development and execution.
2. All financial reports and vouchers for payment and reporting of expenditures will conform to standard A.I.D. regulations and procedures.

7. EVALUATION

The Project will be closely monitored and evaluated on a continuing basis by the CTO with the assistance of the technical staff of the Office of Population. There will also be annual management reviews. Major external evaluations are anticipated at the end of the second year and again at the end of the fourth year. These will use A.I.D. staff and outside experts to make a detailed assessment of project organization and development; project management; project output; and recommendations for project improvement and future activities. The results of the fourth year evaluation will be used to make decisions on project continuation. A similar evaluation schedule is anticipated for the second five years. These evaluations will be carried out and supported through the resources of the Population Technical Assistance project.

8. CONDITIONS AND COVENANTS

Agreements which may be negotiated under this Project and executed by the officer(s) to whom such authority is delegated, in accordance with A.I.D. regulations and Delegations of Authority, shall be subject to the following terms and conditions together with such other terms and conditions as A.I.D. may deem appropriate:

Source and Origin of Goods and Services

Each country where research, training, technical or other assistance takes place under this project shall be deemed to be a cooperating country for the purpose of permitting local cost financing. The aggregate cost of all goods and services under each subagreement in a cooperating country may be procured in the special free world category (Code 935) up to \$750,000 for the purpose of permitting local cost financing.

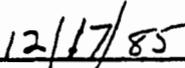
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Contraceptive Development Research (CONRAD)
Certification of the Procurement Plan

I certify that the procurement plan for this Project Paper (936-3044) was developed with full consideration of maximum involvement by minority and women-owned firms, historically Black colleges and universities and minority controlled PVOs in the provision of goods and services, and that the Project is not appropriate for minority or Gray amendment contracting. We know of no minority institutions with an on-going program of the type required or the requisite faculty and facilities. However, to ensure consideration of minority organizations as defined in the Gray Amendment, we will work with the Office of Acquisition and Assistance Management, and the Office of Small and Disadvantaged Businesses, to include all potential recipients on the bidders' list.



Steven W. Sinding
Director, Office of Population



Date

**PROJECT DESIGN SUMMARY
LOGICAL FRAMEWORK**

Project Title & Number: **Contraceptive Research and Development 936-3044**

Life of Project: From FY 86 to FY 95
Total U.S. Funding: \$80,680,000
Date Prepared: 11/85

NARRATIVE SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	HEADS OF VERIFICATION	IMPORTANT ASSUMPTIONS
<p>Department Sector Goal: The broader objective to which this project contributes:</p> <p>To enhance the freedom of individual in LDCs to choose voluntarily the number and spacing of their children.</p>	<p>Measures of Goal Achievement:</p> <p>1) LDC couples' actual and desired fertility are consistent. 2) Safe, affordable contraceptives available to all couples desiring to use them.</p>	<p>1) Census information, vital statistics, demographic and family planning surveys, impact studies. 2) Sector assessments, qualitative verification of actual availability of supplies and services.</p>	<p>Assumptions for achieving goal targets:</p> <p>1) Couples wish to voluntarily choose the number and spacing of children, and will utilize acceptable and accessible means of family planning. 2) A wide variety of FP methods are required to meet LDC needs. 3) Improved methods of family planning be approved by drug regulatory authority and made available to developing country couples.</p>
<p>Project Purpose:</p> <p>To develop improved methods of family planning for use in developing countries.</p>	<p>Conditions that will indicate purpose has been achieved: End of project status.</p> <p>1) 8-10 improved or new methods are either available for use in LDCs or undergoing later stages of clinical testing. 2) Better knowledge of human reproductive processes that will help in development of other new methods.</p>	<p>1) Published articles and final reports of various studies. 2) Reports from other public and private research institutes & pharmaceutical firms. 3) Project & study evaluations and assessments. 4) Drug regulatory authority approval (INDs, PDAs).</p>	<p>Assumptions for achieving purpose:</p> <p>1) Family planning technology can be improved. 2) Research results meet drug regulatory authority requirements for use and/or field testing. 3) Res will result in the adoption of leads public & private research institutions for further testing and production of new methods suitable for use in LDCs.</p>
<p>Output:</p> <p>1) Identification, investigation and/or preliminary testing of new or improved methods 2) Improved knowledge of human reproductive physiology and mechanism of action of new contraceptives. 3) LDC institutions more able to conduct biomedical research on contraceptive development. 4) Information on contraceptive research and development is widely disseminated.</p>	<p>Magnitude of Outputs:</p> <p>1) Research is conducted on about 50 different leads. 2) About 300 research projects/studies are conducted. 3) A network of clinical investigators/institutions is developed in 5-10 LDCs. 4) Ten international workshops and 8-10 regional seminars are held involving a total of 1,000-1,500 participants. 5) 350 scientific publications.</p>	<p>1) Drug regulatory authority approval (INDs, PDAs). 2) Patents, INDs, IDs, issued. 3) Published articles and final reports. 4) Evaluations of projects. 5) LDC clinical investigators and research centers in studies. 6) Conference and workshop reports.</p>	<p>Assumptions for achieving outputs:</p> <p>1) Assessment of state-of-the-art is correct and new methods can be developed given financial resources and time. 2) Scientific personnel are available to conduct research. 3) AID support will facilitate collaboration with other research institutions and private sector industry.</p>
<p>AID/W</p> <p>Salaries and Benefits IAC and Consultants Travel and Per Diem Supplies and Equipment Workshops, Seminars & Publications In-house Research Subagreements Overhead</p> <p align="right">Total</p>	<p>Implementation Target (Type and Quantity)</p> <p align="center">\$000</p> <p>15,500 1,610 3,215 2,440 3,100 10,000 25,335 19,700 80,680</p>	<p>AIDS RECORDS</p>	<p>Assumptions for providing inputs:</p> <p>1) Congressional appropriations support population programming at planned levels. 2) An appropriate institution can be selected to serve as the Cooperating Agency. 3) AID/W technical staff available to manage project. 4) Investigators are interested, available to undertake research.</p>

Next Meeting: Thursday, January 16, at the State Department (in a room to be announced), beginning at 9:30 a.m.

Distribution:

S&T/POP Senior Staff
S&T, N. C. Brady
D. Brennan
Population Sector Council Members
USAID Population Officers
S&T/MGT, E. Caplan

POPULATION SECTOR COUNCIL
MINUTES

Date and Place: December 4, 1985, 9:30 a.m.
SA-18 - 809

Participants: S&T/POP, Steven W. Sinding (Chairman)
AFR/TR/P, John Thomas
ANE/HPN, Charles Johnson
LAC/DR, Maria Mamlouk
PPC/PDPR, Anna Quandt
S&T/POP/R, James Shelton
S&T/POP/R, Jeff Spieler
S&T/POP/R, Laneta Dorflinger
S&T/POP/PDD, Elizabeth Maguire
S&T/MGT, Edward Caplan
S&T/POP, Carl J. Hemmer (Exec. Secretary)

Agenda Issues:

Review of CONRAD. Members reviewed the proposed Contraceptive Research and Development project. S&T/POP/R clarified the role of the project vis-a-vis other contraceptive research and application projects. The Council unanimously approved the proposal with the proviso that more explicit attention be given to the inclusion of fellowships and related support for LDC scientists.

Proposals for Special Studies. Council members agreed to draw up a list of useful studies for discussion at the next Council meeting. Some Council members will meet next week with S&T/POP/R to determine whether a research design can be developed to evaluate a Nigerian experiment with sales of branded vs. unbranded condoms.

December 12 Meeting with Administrator. Sinding and Maguire reviewed the materials prepared for the December 12 briefing, focussed on regional differences between population needs and AID assistance strategies.

"S&T in Development" Award. The Council will determine whether it has a candidate for the award at its January meeting.

Population Officer Assignments. The Council will review worldwide assignments at its next meeting and determine whether the Council has recommendations in this area.

Backstop Code for Nutrition Officers. Caplan alerted the Council to a Khartoum proposal for a common backstop code for health/population/nutrition officers. The Council had no objections to adding nutrition officers to backstop 50.

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