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AGENCY FOR INTERNATIONAL DEVELOPMENT

Washington, D. C. 20523

PROJECT PAPER  
AMENDMENT #1

INDIA: Contraceptive Development  
Reproductive Immunology  
(386-0500)

July 26, 1988

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UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT  
NEW DELHI

CONTRACEPTIVE DEVELOPMENT : REPRODUCTIVE IMMUNOLOGY  
PROJECT PAPER SUPPLEMENT 386-0500

July 20, 1988

UNCLASSIFIED

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PROJECT DATA SHEET

1. TRANSACTION CODE

A = Add  
 C = Change  
 D = Delete

Amendment Number: 1

DOCUMENT CODE 3

2. COUNTRY/ENTITY

INDIA

3. PROJECT NUMBER

386-0500

4. BUREAU/OFFICE

ANE

5. PROJECT TITLE (maximum 40 characters)

Contraceptive Development: Reproductive Immunology

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)

MM DD YY  
 05 31 90

7. ESTIMATED DATE OF OBLIGATION  
 (Under "B" below, enter 1, 2, 3, or 4)

A. Initial FY 85 B. Quarter 3 C. Final FY 88

8. COSTS (\$000 OR EQUIVALENT \$1 = 13.10 )

A. FUNDING SOURCE	FIRST FY 85			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	1,000		1,000	6,600		6,600
(Grant)	( 1,000 )	( 0 )	( 1,000 )	( 6,600 )	( 0 )	( 6,600 )
(Loan)	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
Other U.S.						
1.						
2.						
Host Country		350	350		1,070	1,070
Other Donor(s)						
<b>TOTALS</b>	<b>1,000</b>	<b>350</b>	<b>1,350</b>	<b>6,600</b>	<b>1,070</b>	<b>7,670</b>

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) PN	B430	430		4,300	0	1,300	0	5,600	0
(2) HE	B501	590		100	0	900	0	1,000	0
(3)									
(4)									
<b>TOTALS</b>				<b>4,400</b>	<b>0</b>	<b>2,200</b>	<b>0</b>	<b>6,600</b>	<b>0</b>

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 BR RPOP  
 B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

To support laboratory studies in the area of reproductive and disease related immunology.

14. SCHEDULED EVALUATIONS

Interim MM YY MM YY Final MM YY  
 06 87 03 90

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000  941  Local  Other (Specify)

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a 6 page PP Amendment)

Controller, USAID, New Delhi

Date signed 7-22-88

17. APPROVED BY

Signature: Robert N. Bakley  
 Title: Robert N. Bakley, Director, USAID/New Delhi

Date Signed MM DD YY

18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION

MM DD YY

## PROJECT AUTHORIZATION

INDIA

CONTRACEPTIVE DEVELOPMENT: REPRODUCTIVE IMMUNOLOGY  
PROJECT NUMBER 386-0500

Pursuant to Sections 103, 104 & 106 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the Contraceptive Development: Reproductive Immunology Project (the "Project") for India (the "Cooperating Country"), involving planned obligations of not exceeding Six million Six Hundred Thousand U. S. Dollars (\$6,600,000) over a four years and eleven month period from the date of the original authorization, subject to the availability of funds in accordance with the A.I.D OYB/Allotment process, to help finance the local and foreign currency costs of the Project.

The Project consists of providing assistance to the Cooperating Country to finance Indo-U.S. Collaborative Research in contraceptive development and research in immunology.

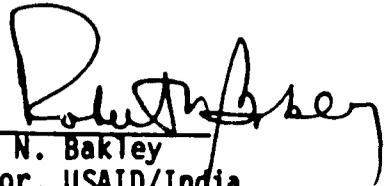
The Cooperating Country intends to contribute the Rupee equivalent of an estimated One million and Seventy Thousand U.S. Dollars (\$1,070,000) to finance local currency costs associated with the Project.

The Project Agreement for the Project, 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 essential terms, conditions and covenants, together with such other terms and conditions as A.I.D. may deem appropriate.

- A. SOURCE AND ORIGIN OF GOODS AND SERVICES Goods and services, except for ocean shipping, 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. Ocean shipping financed by the A.I.D. under the Project shall be financed only on flag vessels of the United States and the Cooperating Country, except as A.I.D. may otherwise agree in writing.
- B. COVENANTS: The GOI will agree to jointly establish with USAID/I the following:
  1. An Indo-U.S. Joint Working Groups (JWGs) with Technical Coordinators to provide the required management for the project and to insure that a Peer Review Process is followed prior to the approval of all Collaborative Research proposals to be funded under the project, i.e. the U.S. JWG will utilize the services of the National Institute of Health (NIH) while the DBT will establish its own mechanism for the provision of Peer Review. The JWG's procedures for approval of "Center Grants" will accept applications for funding proposals under the project only from institutions selected under the "Center Grants";

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2. A stipulation that a maximum of 45% and a minimum of 15% of the bilateral project funds, over any two year period, will be provided to any one of the selected institutions; and
3. A requirement that project funding will be used to finance only work in areas of contraceptive development which are consistent with the U.S. Foreign Assistance Legislation and in general disease-related immunology.

Signed   
Robert N. Bakley  
Director, USAID/India  
Dated 26 July 88



UNITED STATES AGENCY for INTERNATIONAL DEVELOPMENT

NEW DELHI, INDIA

July 22, 1988

ACTION MEMORANDUM TO THE DIRECTOR USAID/INDIA

FROM: Steven J. Freundlich, PRJ *SA*

SUBJECT: Contraceptive Development: Reproductive Immunology (CD:RI)  
#386-0500 - Project Authorization Amendment

**ACTION:** You are requested to approve and authorize: (1) a \$2.2 million increase in the Life-of-Project (LOP) funding level of the Contraceptive Development: Reproductive Immunology (CD:RI) project; (2) a twenty-two month extension of the Project Assistance Completion Date (PACD) from July 31, 1988 to May 31, 1990; (3) a change in the name of the project to the "Contraceptive Development and Research in Immunology" project; and (4) a restructuring of the project as described in the attached PP Supplement.

**BACKGROUND:** The original design of the Family Planning Communications and Marketing (FPCM) project (#386-0485) provided an estimated \$1.0 million to support biomedical research on reproductive immunology. Following the signing of the FPCM Project Agreement the GOI, for administrative reasons, requested USAID/I to split out the CD:RI component of the FPCM project into a completely separate project. These administrative reasons revolved around the fact that the implementing agency for the FPCM project was Ministry of Health and Family Welfare (MOHFW), whereas the Contraceptive Development: Reproductive Immunology (CD:RI) component of the project was to be implemented by the Ministry of Science and Technology (MOS&T).

Based on the GOI request, the CD:RI project (#386-0500) was authorized for \$1.0 million on March 25, 1985. The Project Activity Completion Date (PACD) of the project was May 31, 1988. At that time, a separate PP was not required for the CD:RI project in that AID/W agreed that the PID and pertinent sections of the FPCM PP would suffice as having met the documentation requirements for authorization of a separate CD:RI project.

The original objectives of the CD:RI project, "...to support Indo-U.S. collaboration in biomedical research, with emphasis on reproductive immunology...", were fully met. However, implementation on the Indian side of the project was limited to only one institution, the National Institute of Immunology (NII) and project funds were not sufficient, nor was the Project Agreement flexible enough, to support sufficiently the U.S. side of collaborative research efforts that the project was to finance.

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Furthermore, the project had a somewhat narrow focus on reproductive immunology and contraceptive vaccine development which was not fully consistent with the objectives of providing: (a) a wider range of safe, acceptable and effective methods of contraception for couples who wish to practice voluntary family planning; and (b) the necessary flexibility to support complementary research and training in disease-related immunology.

In addition, the management structure, review process and the use of U.S. based implementing organizations (PARFR, Northwestern University and CONRAD, Eastern Virginia Medical School), under the unilateral obligations in the project, did not fully satisfy the requirements of the NII or those of the MOS&T, the implementing agency of the GOI. For example, there was no reason to have U.S. scientists acting as procurement agents for Indian scientists.

Therefore, USAID determined that a PP Supplement should be developed to restructure the original CD:RI project.

DISCUSSION: After extensive discussions with the concerned GOI implementing agencies, the DEA and appropriate AID/W officials, a PP Supplement has been developed which restructures the existing project. The PP Supplement recommends the following:

1. The authorization of an additional \$2.2 million of bilateral grant funds for a new LOP funding level of \$6.6 million;
2. The amendment of the original Scope of Work of the project to allow for a program of "Center Grants" to be given to between 3-6 Indian institutions which will be selected by the Department of Biotechnology (DBT) of the MOS&T, with the concurrence of USAID/I. These grants are to be for the purpose of providing: (a) Indo-U.S. Collaborative Research Awards, (b) long-term, Young Investigator Awards including funding for Re-entry Grants; (c) Science Management Awards, and (d) Core Support Awards for general institution strengthening;
3. The provision of project management by the Indo-U.S. Joint Working Groups (JWGs) with Technical Coordinators. Such management will insure that a Peer Review Process is followed prior to the approval of all Collaborative Research proposals to be funded under the project, i.e. the U.S. JWG will utilize the services of the National Institute of Health (NIH) while the DBT will establish its own mechanism for the provision of Peer Review. Applications for funding proposals under the project shall only be entertained from institutions selected under the "Center Grants" program described above;
4. The provision of no more than 45% nor less than 15% of bilateral project funds, over any two year period, to any one of the selected institutions under the Center Grants program. Recognizing the necessity of implementation flexibility, this recommendation of the PP Supplement shall be an objective but not a strict requirement of the amended project. As part of the requirements for utilizing the

project funding, the recipient institutions will be able to work in all areas of contraceptive development consistent with the U.S. Foreign Assistance Act Legislation and in general disease-related immunology;

5. The amendment of the title of the project from "Contraceptive Development: Reproduction Immunology (CD:RI)" to "Contraceptive Development and Research in Immunology (CD&RI)"; and
6. The extension of the PACD of the project from July 31, 1988 to May 31, 1990.

In sum, the PP Supplement broadens the scope of the project and increases the probability that Indo-U.S. Collaborative Research will make significant advances in contraceptive development and research in immunology. Furthermore, the restructured project insures that the project will more closely adhere to USAID/I's recently articulated Country Development Strategy Statement (CDSS) in Science & Technology. Notwithstanding this broadening the original project purpose and goals remain unchanged.

FAA SECTION 612 (b): When the USAID/I program was re-established in 1978, it was determined that as an exception the India program could provide project funded foreign exchange to finance eligible local cost expenditures, as opposed to funding such costs exclusively from U.S. government owned excess Rupees. This determination was reaffirmed during the FY 88 Annual Budget Submission (ABS) reviews in AID/W.

In accordance with past practice, your signature on the attached Project Authorization will provide the required FAA Section 612 (b) certification to use foreign exchange to finance local costs under the subject project.

CONGRESSIONAL NOTIFICATION: A Congressional Notification (CN) was forwarded to the Congress on July 6, 1988 and the CN expired on July 21, 1988.

CONDITIONS PRECEDENT: All the Conditions Precedent (CPs) to disbursement of funds under the original Project Agreement have been met and no additional CPs will be required to implement the restructured project.

COVENANTS: All the Covenants under the original Project Agreement have been met. However the restructured project will require that the GOI agree to the following covenants:

1. That the Indo-U.S. Joint Working Groups (JWGs) with Technical Coordinators will provide the required management for the project and that such management will insure that a Peer Review Process is followed prior in the approval of all Collaborative Research proposals to be funded under the project, i.e. the U.S. JWG will utilize the services of the National Institute of Health (NIH) while the DBT will

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establish its own mechanism for the provision of Peer Review. Applications for funding proposals under the project shall only be entertained from institutions selected under the "Center Grants" program which is to be established under the project; and

2. That no more than 45% and no less than 15% of the bilateral project funds, over any two year period, will be provided to any one of the selected institutions; and
3. That project funding will only be used to finance recipient institutions work in areas of contraceptive development which are consistent with the U.S. Foreign Assistance Legislation and in general disease-related immunology.

AUTHORITY: Redlegation of Authority 652, dated September 1, 1986 authorizes the Director of USAID/I to amend projects if the amendment: does not result in a total LOP funding level of more than \$30.0 million; extend the PACD by more than two years; or extend the LOP for a period of more than 10 years. This amendment: extends the PACD for a only 22 months for a total extension of two years; increases the LOP to a total of 4 years and 11 months; and brings the total LOP funding level to \$6.6 million. Therefore, you have the authority to approve this PP Supplement and amend the existing Project Authorization for this project.

RECOMMENDATION: That you sign the attached Project Authorization Amendment and the PP Supplement, Project Data Sheet and thereby authorize: (1) a \$2.2 million increase in the life-of-project funding level of the Contraceptive Development: Reproductive Immunology project; (2) a twenty-two month extension of the Project Assistance Completion Date (PACD) from July 30, 1988 to May 31, 1990; (3) a change in the name of the project to the "Contraceptive Development and Research in Immunology" project; and (4) a restructuring of the project as described in the attached PP Supplement.

Approved *Robert B. Boy*  
 Disapproved \_\_\_\_\_  
 Dated 26 July 88

ATTACHMENTS:

- Project Authorization Amendment
- PP Supplement
- PP Data Sheet
- Scope of Work

CLEARANCE:

- PRJ, GThompson (DRAFT)
- BRD, JSherry (DRAFT)
- DPP, KKBabian *[Signature]*
- CO(A), GWBarwick *[Signature]*
- DD(A), RWBeckman *[Signature]*

APP: 72-1181021  
 EPC: QDPA-88-27386-KG-13  
 RES.#P800054 \$ 1,300,000.00

APP: 72-1181021  
 BPC: QIHA-88-27386-KG-13  
 RES.#P800055 \$ 900,000.00

CONTRACEPTIVE DEVELOPMENT : REPRODUCTIVE IMMUNOLOGY

PROJECT PAPER SUPPLEMENT

I. IMPLEMENTATION PROBLEMS:

- A. On July 27, 1983, the Administrator of the Agency for International Development authorized a \$34.0 million loan and a \$14.0 million grant for the Family Planning Communications and Marketing (FPCM) Project (386-0485). The project included a \$1.0 million component designed to support biomedical research on reproductive immunology. Subsequent to conducting a review of the implementation of this component the GOI requested A.I.D. to treat the reproductive immunology activity as a separate project rather than as a component of the FPCM project. The reason for this request was administrative since the FPCM project was under the jurisdiction of the Ministry of Health and Family Welfare whereas the Contraceptive Development: Reproductive Immunology (CD:RI) component of that project was under the Ministry of Science and Technology.
- B. USAID agreed to treat the CD:RI component as a discrete project. To simplify the approval process and accelerate the obligation of funds, USAID requested AID/W: to authorize a \$1.0 million grant for new the CD:RI project; and to waive the requirement for the development of a separate Project Paper, because the original PID and the pertinent sections of the FPCM PP met the PP requirement for the project. Per a memorandum signed on December 28, 1984 the Assistant Administrator, Bureau for Asia, concurred with both USAID/I requests and the project was authorized on March 25, 1985.
- C. The original objectives of the project are being met. AID support has resulted in: (a) the purchase of supplies and equipment for the National Institute of Immunology (NII); (b) the short-term (2-7 month) scientific exchanges/training of eight NII investigators; (c) a long-term (one year) sabbatical for one investigator to visit nine collaborating laboratories in the U.S.; (d) management training of the NII administrator in the U.S.; (e) two Indo-U.S. workshops; and (f) numerous scientific publications. These activities were all related to enhancing knowledge in reproductive immunology with the long-term objective of developing contraceptive vaccines.
- D. However, the structure of the project was too limited to facilitate rapid progress and maximize the achievement of the broader objective of supporting Indo-U.S. collaboration in biomedical research on contraceptive development and research in immunology. Furthermore the project was not fully consistent with the objective of developing a wide variety of safe, acceptable and effective methods of family planning, nor did it

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leave room to support general applied research in disease-related immunology due to: the limitation of providing support to only one recipient Indian institution, the NII; the lack of sufficient funds to support the U.S. side of collaborative research projects; and a Scope of Work that was confined to contraceptive vaccine development with all of its inherent technical, political and practical problems.

- E. In addition, the management structure of the project was not optimal in that a good Peer Review mechanism for evaluating NII research had not been established and scientists at the U.S. based AID/W grantee (CONRAD, Eastern Virginia Medical School) were expected to act as financial managers and procurement agents for the NII.

## II. PROPOSED SOLUTIONS:

- A. In view of these implementation problems, USAID/I proposes to restructure the project to support general contraceptive development research in India, the U.S. and elsewhere, as follows:
1. Authorize an additional grant of \$2.2 million in bilateral grant funds for activities briefly described under item 3 below;
  2. Expand the key features of the Scope of Work for the CONRAD Program Buy-In (See Attachment 1: Statement of Work for details);
  3. Amend the CD:RI Project Agreement to include:
    - a) the establishment of an Indo-U.S. Joint Working Group with Technical Coordinators to manage the bilateral program at the three to six participating Indian institutions which will receive Center Grants, each not more than 45% or less than 15% of the total funds available under the project. The Center Grants will be composed of some or all of the following: (i) Collaborative Research Awards with U.S. institutions; (ii) longterm, Young Investigators Awards with Re-entry Grants which include funds for revisits to the collaborating laboratories; (iii) Science Management Awards, for mid-career scientists; and (iv) Core Support Awards, which are linked on a dollar-to-dollar basis to funds spent on Young Investigators, and Science Management awards;
    - b) the development of an Indian and a U.S. Peer Review Process to evaluate collaborative research proposals;

- c) the extension of the PACD of the project from July 30, 1988 to May 31, 1990 to satisfactorily accomplish the activities under the project;
- d) Include the financing of only those proposals which are sanctioned on or after the Project Agreement Amendment has been executed; and
- e) Include the following proposed target grants and funding for the final two years of the project:

<u>GRANTS</u>	<u>FUNDING</u>
i) 3 to 6 grants under the USAID- DBT Indian Center Grants program	\$ 2.2 million
ii) CONRAD support for research in India using Buy-In funding	\$ 1.0 million
iii) CONRAD support for research in the U.S. and elsewhere in support of bilateral approved CDRI projects	\$ 1.0 million
iv) Other AID, non-AID and CONRAD support for research in India, the U.S. and elsewhere in support of bilaterally approved CDRI project.	\$ 1.0 million

4. The achievement of the above targets will require a continued and concentrated effort on the part of USAID/I, the DBT, and the Science and Technology Bureau in AID/W to establish the JWG's and select appropriate Technical Coordinators.

5. The original project purpose and goal are to remain unchanged.

**III. FINANCIAL PLAN:**

An illustrative budget for both the bilateral grant to the GOI and the unilateral funds provided to CONRAD is attached. The purposes for which the unilateral funds will be used are spelt out in Attachment I. The additional bilateral grant funds of \$2.2 million will be used for financing (a) grants to US and Indian institutions for the purposes outlined in Section II of this PP supplement, and (b) the costs of the JWG and Technical Coordinators as agreed to later in a Project Implementation Letters. It is not known at this time how many institutions will be involved or the number of central grants that will be made. This will be determined as the project implementation progresses. Similarly, the details of equipment and services to be procured will be known only after the central grants are finalized. Consequently, a detailed cost estimate or implementation plan for each project component has not been developed.

The methods of Implementation and Financing for the project are shown below:

<u>Methods of Implementation</u>	<u>Methods of Financing</u>	<u>Estimated Cost (\$000)</u>
HC Institutions * Grants	HC Reimbursement	\$2,200
U.S Institutions (PARFR) Coop. Agreement	LOC	\$1,000
U.S Institutions (CONRAD) Coop. Agreement	LOC	\$3,400
		<u>\$6,600</u>

The expenditure, if any, that may be incurred for JWG and Technical Coordinators cannot be estimated at this time. It is expected that any such expenditure will also be financed through reimbursements to the GOI.

**IV. AUDIT**

The Project will be implemented by the Department of Biotechnology (DBT), GOI Ministry of Science & Technology, which is subject to the contracting, audit, and payment verification procedures and guidelines prescribed by the GOI. As stated in USAID's initial submission of the 'Mission Financing Policy and Procedures as of December 31, 1984',

"...USAID has reasonable assurance, based on thirty odd years experience, that the Government and its departments have the necessary financial and management capability to implement projects."

Although USAID has not had any recent reviews of the GOI's payment verification systems and practices, USAID is generally satisfied with their capability to implement projects. In fact, based on our experience with implementation of other AID projects, USAID has no reason to doubt their administrative, audit, and/or financial management capabilities. USAID does not feel any special need for an audit beyond the standard GOI audit coverage and therefore no funds are being earmarked under the Project for that purpose.

The DBT and participating subgrantees will maintain separate books and records for the grant funds. These shall provide adequate records of the activities financed under the Project relating to the administration, monitoring and evaluation; the nature and extent of solicitation of prospective suppliers of required goods and services; the basis of award of Host Country contracts; and overall progress. These will be available for audit by AID. In addition, if the sub-grantee is a non-GOI entity, its books and records will be audited by a Chartered Accountant each project year.

## ATTACHMENT I

### I. STATEMENT OF WORK - CONRAD BUY-IN

- A. Objective: The objective of this buy-in is to support research and related activities conducted under the Contraceptive Research and Development (CONRAD) Project, Eastern Virginia Medical School, Norfolk, Virginia, which is aimed at developing new and/or improved methods of fertility regulation for use in less developed countries (LDCs). Support will be provided to collaborating investigators and institutions in India and the U.S., and to investigators in the U.S. and elsewhere in support of Indian priorities in contraceptive development.
- B. Scope of Work: One of the ways of meeting the challenge of making family planning more widely available and acceptable is through the improvement of existing methods of fertility regulation and the development of new ones. Some methods that may find immediate application in LDCs are entirely lacking, e.g. a male pill, contraceptive vaccines, and reversible sterilization for men and women.

The scope of research supported under this buy-in will range from synthesis or isolation of new compounds, to laboratory and preclinical toxicity studies in animals, to the first two phases of clinical trials in volunteers. An area of special emphasis under this buy-in is so-called mission oriented or fundamental applied research. Such research has a specific goal in mind, e.g., the development of a vaccine against sperm antigens or identification of novel spermicides with viricidal properties, but owing to important gaps in knowledge, a certain amount of applied basic research needs to be conducted.

The funds provided under this buy-in are not restricted to any particular contraceptive research and development areas. There are numerous areas for potential collaboration between the U.S. and Indian scientists and institutions. These include, but are not limited to:

1. Contraceptive Vaccines - When the USAID bilateral CD:RI project was evaluated in February 1987, it was recognized that, because of insufficient funding, it was difficult to attract U.S. investigators/ collaborators to develop and conduct joint research with Indian investigators. Funds under this buy-in will be used to support associated research costs in U.S. laboratories working on collaborative projects with India institutions, or on related research. Funds will also be used to conduct activities which cannot be done in India, e.g. animal toxicity studies required for FDA approval of a new vaccine.

2. Spermicides - Investigators in India have screened about 2500 plant products for spermicidal activity and found about 25 active leads. One lead, Consap, has been claimed to show some promise but needs much more work. Indian investigators have also synthesized a series of novel spermicides which apparently show much greater activity in vitro than the industry standard, Nonoxynol-9. Confirmation of biological activity and animal toxicity testing need to be undertaken before clinical trials can begin; some of this work can be done collaboratively with U.S. institutions to obtain FDA approval. In addition, some novel compounds related to gossypol have been synthesized which may prove to be orally active in men: considerable collaborative research on the testing of these compounds is required.
3. Delivery Systems and Devices - Indian investigators have expressed interest in collaborating with U.S. institutions on the development and testing of new delivery systems. This would include long acting injectable microspheres and microcapsules for female and male contraception, new delivery systems for spermicides, transdermal delivery of steroids, new biodegradable implants, reversible and/or non-surgical sterilization techniques for women and men, and new methods for lactating mothers.
4. Technology Transfer - Technology transfer is of particular interest to the GOI, Department of Biotechnology, and to A.I.D. The GOI has recently instituted a policy that is aimed at securing rights to produce locally products or technology that it assesses. Potential areas for collaboration between CONRAD and Indian institutions include the synthesis of compounds, such as peptide hormones; molecular biology and genetic engineering; pharmaceutical formulation and delivery systems; local production of reagents and immunodiagnostics; and establishment of good laboratory practices (GLP) and good manufacturing practices (GMP).
5. Workshops, Seminars and International Meetings - Workshops, seminars and meetings would be convened in India, the U.S.A. and elsewhere to bring together scientists and researchers to present their work and exchange ideas on research and developments related to fertility regulation and contraceptive development. Indian scientists have expressed interest in convening and/or attending meetings on such topics as advances in long acting contraception, research on male methods of fertility regulation, intrauterine contraceptive devices, oral contraceptives, advances in non-surgical sterilization, and the status of gonadal peptides and releasing hormone analogs for male and female contraception.

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6. Equipment and Supplies - Investigators in LDCs, and particularly in India, suffer from the lack of foreign currency, especially dollars, to purchase equipment and supplies needed to conduct biomedical research. Frequently, for want of a specific chemical, or an inexpensive spare part for a laboratory instrument, some research projects come to a standstill. Funds under this project can be made available to institutions in India conducting contraceptive research to purchase essential spare parts, supplies and chemicals, and small pieces of equipment.
  7. Technical Assistance - Funds will be made available to provide technical assistance to Indian investigators and institutions. Such assistance could be for evaluating programs and reviewing projects, developing research protocols, providing short-term consultants or in-country training, for conducting confirmatory studies in the U.S. or supporting research for Indian investigators which cannot be conducted in India.
- C. Technical Review and Approval: All proposals and related activities to be supported under this buy-in will be reviewed by the CONRAD staff, the CONRAD Technical Advisory Committee, as appropriate, and A.I.D./W. When necessary, amendments will be funded under cost-reimbursible subagreements. The CONRAD staff will be responsible for monitoring all research and making administrative arrangements for supporting other activities such as workshops, training, and purchase of supplies and equipment. As necessary, GOI clearance will be obtained prior to supporting projects in India.
- D. Reporting and Evaluation: All investigators/institutions supported will be required to submit semi-annual progress reports summarizing the project's objectives, results, accomplishments, changes in Scopes of Work and problems/solutions. As appropriate large projects supported under this buy-in will be evaluated by CONRAD staff and technical advisors, as needed. The CONRAD program will include, in its semi-annual reports to A.I.D., a description, status report and financial statement of the activities supported with the funds provided under this buy-in.

**CONTRACEPTIVE DEVELOPMENT AND RESEARCH IN IMMUNOLOGY (386-0500)**

Illustrative Budget for Grant Funding  
by Project Elements up to and including Second Amendatory Agreement  
(Data in \$ 000)

Project Elements	A.I.D. Grant			GOI Contribution		Total
	LC	FX	Total	LC	FX	
<b>A. BILATERAL GRANT</b>						
1. Direct Grant to Program for Applied Research and Fertility Reduction (PARFR)	0	1,000	1,000	330	0	1,330
2. Central Grants	<u>1,200</u>	<u>1,000</u>	<u>2,200</u>	<u>740</u>	<u>0</u>	<u>2,940</u>
<b>SUB-TOTAL</b>	<b>1,200</b>	<b>2,000</b>	<b>3,200</b>	<b>1,070</b>	<b>0</b>	<b>4,270</b>
<b>B. UNILATERAL</b>	<u>1,500</u>	<u>1,900</u>	<u>3,400</u>	<u>0</u>	<u>0</u>	<u>3,400</u>
<b>TOTAL</b>	<b>2,700</b>	<b>3,900</b>	<b>6,600</b>	<b>1,070</b>	<b>0</b>	<b>7,670</b>
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**SUMMARY BY A.I.D. COST CATEGORIES FOR A.I.D. GRANT**

1. Technical Assistance	2,000
2. Training	3,000
4. Other Costs	<u>1,600</u>
<b>TOTAL</b>	<b>6,600</b>
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