

PD - AAR - 659 41061

QPC

PII -- GRANT
EM/BFD
GC/ASIA
ASIA/PD:FLH

AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C. 20523

PROJECT PAPER

INDIA

CONTRACEPTIVE DEVELOPMENT: REPRODUCTIVE IMMUNOLOGY

PROJECT 386-0500

MARCH 1985

PROJECT AUTHORIZATION

INDIA

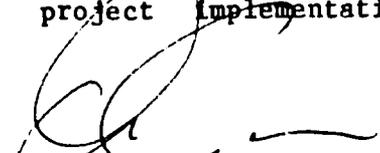
Contraceptive Development:
Reproductive Immunology
Project No. 386-0500

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the Contraceptive Development: Reproductive Immunology Project for India (The "Cooperative Country") involving planned obligations of not to exceed One Million United States Dollars (\$1,000,000) in grant funds over a three year period from 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 Project is intended to support Indo-U.S. collaborative research in reproductive immunology. Project funds will finance research costs, international travel for participating scientists, and equipment and supplies. The Project will not finance any activities related to voluntary sterilization.

3. The Project 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 covenants, together with such other terms and conditions as A.I.D. may deem appropriate.

- a. The Cooperating Country agrees that funding provided by A.I.D. for this project shall be disbursed in reimbursement for costs incurred, or in advances to segregated accounts, to ensure that none of the funds furnished by A.I.D. for the project can be used to support abortion.
- b. The Cooperating Country agrees that funding provided by A.I.D. for this project will not be used for abortion and/or menstrual regulation (MR) related activities including specifically but not limited to, information, education, lobbying, training or communications programs that seek to promote abortion and/or MR as a method of family planning. A.I.D. may, from time to time, further specify prohibited abortion and/or MR related activities by project implementation letters.


Owen Cylke
Director
USAID/India

Date 3/25/65

PROJECT DATA SHEET

1. TRANSACTION CODE

A = Add
 C = Change
 D = Delete

Amendment Number

DOCUMENT CODE

3

2. COUNTRY/ENTITY

INDIA

4. BUREAU/OFFICE

ASIA

3. PROJECT NUMBER

386-0500

5. PROJECT TITLE (maximum 80 characters)

CONTRACEPTIVE DEVELOPMENT:
 REPRODUCTIVE IMMUNOLOGY

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)

MM DD YY
 05 31 88

7. ESTIMATED DATE OF OBLIGATION

(Under "B." below, enter 1, 2, 3, or 4)

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

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

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

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		-0-	-0-	900	-0-	900	-0-
(2) HE	B501	590		-0-	-0-	100	-0-	100	-0-
(3)									
(4)									
TOTALS				-0-	-0-	1,000	-0-	1,000	-0-

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

430

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 immunology.

14. SCHEDULED EVALUATIONS

Interim MM YY MM YY Final MM YY
 06 87 03 88

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000 941 Local Other (Specify)

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

17. APPROVED BY

Signature

Title

Owen Cylke
 Director, USAID/India

Date Signed

MM DD YY
 03 25 85

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

MM DD YY

INTRODUCTION

Contraceptive Development: Reproductive Immunology

(386-0500)

In FY 1983, the Acting Administrator authorized a \$34 million loan and a \$14 million grant for the Family Planning Communications and Marketing Project. The project included a \$1 million component designed to support biomedical research on reproductive immunology. This component was subsequently deleted by an amendment to the authorization to allow the Government of India additional time for review. Upon completion of its review, the GOI requested that A.I.D. proceed with the reproductive immunology activity but as a separate project rather than as a component of the FPCM project. The reason for the separation is administrative. The FPCM project is under the jurisdiction of the Ministry of Health and Family Welfare whereas responsibility for the Contraceptive Development Reproductive Immunology Project will fall under a different entity, the Ministry of Science and Technology.

USAID agreed to treat reproductive immunology as a discrete project and per 84 New Delhi 25097 asked AID/Washington for the authority to authorize \$1 million for a Contraceptive Development: Reproductive Immunology Project. To simplify the approval process and accelerate the obligation date, USAID also requested that no project paper be required for the CD:RI Project and that the original PID and the pertinent sections of the FPCM PP could suffice for this PP requirement. Per a memorandum signed on December 28, 1984, the Assistant Administrator, Bureau for Asia, concurred with both USAID requests.

Attached are the sections of the FPCM project paper which discuss the reproductive immunology activity, 84 New Delhi 25097, the AID/W approval documentation, and the proposal submitted by the Indian National Institute of Immunology to the GOI for an Indo-U.S. collaborative program in contraceptive development. These documents will constitute the project paper for the Contraceptive Development: Reproductive Immunology Project.

As happens with most AID projects, the passage of time has led to a few small alterations in the original design. The general intent of the project, however, remains the same. Most important, the focus of research is more narrow but within the bounds of what was proposed in the FPCM PP. It is likely that the CDRI project will support research on sperm antigens, egg antigens, and molecular biology approaches for the cloning and expression of gametes. Also not

anticipated during the earlier design were the two binational committees that will be set up for scientific oversight of the research program, i.e., a clearance committee responsible for obtaining the appropriate approvals from the respective governments and a technical advisory committee responsible for defining needs, approving protocols, and reviewing budgets. (The first meeting of the binational technical advisory committee is scheduled for June 1985. At that time, committee members will develop an implementation plan for the project as well as target dates for meeting implementation objectives.) Finally, it is likely that the Rockefeller Foundation rather than the Program for Applied Research in Fertility Regulation at Northwestern University will manage the A.I.D. financed inputs of the project. The entire \$1 million life of project funding will be committed to Rockefeller through a Cooperative Agreement. Disbursement will be made upon the review and approval of vouchers submitted by Rockefeller.

CONTRACEPTIVE DEVELOPMENT: REPRODUCTIVE IMMUNOLOGY

(386-0500)

Excerpts from Family Planning Communications and Marketing Project

(386-0485)

Project Summary, Rationale, and Description

The project will support Indo-U.S. collaboration in biomedical research, especially in reproductive immunology. This small but important component will help India continue the search for better and more appropriate fertility regulation methods, and will capitalize on India's unique capabilities in this field. New methods of fertility regulation will increase choices for couples in India and elsewhere, and may provide a "safety net" if current program methods fall short. The budget for this component is \$1 million to cover costs in the U.S. for materials, workshops and studies.

Outputs

Biomedical collaboration will be undertaken as coordinated investigations between leading Indian and U.S. institutions based on the mutual interests of Indian and U.S. institutes and of individual scientists, particularly in the field of immunology of reproduction. This will include investigators in India from the Indian National Institute of Immunology, the Post Graduate Institute of Medicine at Chandigarh, the Institute for Research and Reproduction at Bombay, the Indian Institute of Science at Bangalore, the Central Drug Research Institute at Lucknow; and in the U.S., investigators at the Department of Biochemistry and Molecular and Cell Biology, Northwestern University, Oregon Primate Center, the International Committee for Contraceptive Research (Population Council) and at the National Institute of Health, Bethesda, Maryland, among others.

Immunological approaches to human fertility regulation are now feasible based on recent biological advances and the new technologies of human mono-clonal antibody production and genetic engineering. Indo-U.S. collaboration already exists between the Indian Institute of Immunology and International Committee for Contraceptive Research focusing on post-fertilization techniques.

This project will support research only on pre-fertilization methods. Because of strong Indian resources, expertise and interest in this specific research area and because of the recent advances in the U.S. in the field of reproductive immunology (especially in the area of andrology), two complementary approaches will be taken. Both involve support to U.S. institutions to sustain U.S. costs of collaboration in India and dollar costs of Indian participation in the joint program. The first will involve a U.S. Task Force with participation of Indian scientists and the second will involve targeted research projects. The Task Force will convene to prepare workscopes

for U.S. contractors and studies to be undertaken with the GOI Department of Science and Technology (DST). This Task Force will determine the topics to be studied. AID/ST/POP, USAID/New Delhi and representatives of the GOI/DST will select an appropriate U.S. institution to serve as prime contractor and convenor of the U.S. Task Force. Due to their apparent predominant experience this seems likely to be the Program for Applied Research in Fertility Regulation (PARFR) at Northwestern University, Evanston, Illinois. Likely topics for targeted research are as follows. The first concerns a sperm-specific antigen which has been successfully used to immunize mice, rabbits and baboons against pregnancy. Studies may be supported to test its antigenicity with synthetic adjuvants in monkeys, to test the minimum antibody needed via passive immunization to prevent fertility, and finally to see if this specific antigen can be produced synthetically.

The second targeted research may study specific sperm antigens previously identified through the study of sera of infertile couples. Passive immunization studies will be conducted to determine titers necessary to prevent fertility. Subsequently conjugation of specific antigens may be undertaken for active immunization.

The third targeted research may be directed towards an antigen contained in the zona pellucida surrounding the egg. Studies are needed to define the antigen biochemically, and this leads into the fourth targeted area of immunopathology studies. These safety studies will most appropriately be carried out at different Indian institutions with special arrangements for pathological studies.

The fifth targeted area will transfer the technology of cryopreservation of sperm and of antigens. This will have both veterinary value as well as importance for human egg and sperm preservation.

New computer simulation techniques developed in the U.S. may become the subject of joint studies and technology transfer.

Finally, and perhaps most promising, this project will study the effectiveness of the IgA secretory antibodies in cervical mucus, which, if effectively demonstrated, will lead to monoclonal IgA antibody production for bonnet monkeys -- a major step towards development of the technology for humans.

It is anticipated that the several Indian institutes with scientists and laboratories working on reproductive immunology, members of which make up a complementary Indian Task Force, will communicate freely with U.S. reproductive immunologists and the NIH for long range research planning. The task force approach in reproductive immunology has been singled out for emphasis by the Indo-U.S. Senior Scientific Panel at the February 1963 meeting in New Delhi.

Financing Procedures

A.I.D. will finance travel to and per diem of U.S. scientists in India and travel and per diem of Indian scientists in the U.S. The cost of workshops in India will be covered by the GOI; those in the U.S. will be covered by A.I.D. Costs of exchanges of materials between laboratories will be borne by the country of origin. The U.S. costs of this collaboration may be covered by USAID obligations to an existing centrally funded contractor.

Implementation Plan

Start-up Actions

The key events which must occur during the first few months after the Project Agreement is signed are conclusion of funding agreements with U.S. institutions on biomedical research.

Management for Demographic Analysis and Biomedical Research

These components fall outside the purview of the MOHFW. Demographic analysis will be implemented under the aegis of the Registrar General/Commissioner of the Census of the Ministry of Home Affairs, and the U.S. Bureau of Census and East-West Population Institute. Biomedical research likewise involves the Department of Science and Technology, the Institute of Immunology and the Indian Task Force on Reproductive Immunology on the Indian side and such U.S. institutions as the Program for Applied Research in Fertility Regulation (PARFR) at Northwestern University, Evanston, Illinois. These will be arranged by supplementing AID's existing PASA with BuCen and the existing agreements with the East-West Center and Northwestern University.

Monitoring Plan

Possible Problem Areas and USAID Monitoring Actions

- delays in demographic analyses and bio-medical research: detailed work plans and schedules will likewise be prepared. Progress against these schedules will be monitored continuously.

Illustrative Calendar of Monitoring Actions by USAID Staff

In order to watch for and address these potential or anticipated problems, USAID plans roughly the following monitoring schedule. The schedule will change as actual problems emerge and as implementation patterns evolve.

<u>July to September 1983</u>	<u>Work Days</u>
Interact with MOHFW, NIHFW	10
" " Governing board, CMO	10
" " IEC Task Force	3
" " RG Census	1
INTERACT WITH BIOMED CONTRACTOR & INDIAN COUNTERPART	<u>2</u>
T O T A L	<u>26</u>

October to December 1983

Interact with Counterparts	20
" " U.S. Demographic Contractors & Indian Counterparts	4
INTERACT WITH U.S. BIOMED CONTRACTOR & INDIAN COUNTERPARTS	<u>3</u>
T O T A L	<u>27</u>

January to March 1984

Interact with Counterparts	15
Visit 5 regional offices @ 2 days each)	10
Visit NIHFW Workshops	1
Visit CMO physicians Workshops	3
Monitor mass mailing	5
Visit demographic analysis workshop	<u>1</u>
T O T A L	<u>35</u>

April to June 1984

Interact with Counterparts	15
Visit 2 Regional Offices (@ 3 days)	6
Review CMO budget	1
Monitor workshop proceedings	2
MONITOR BIOMEDICAL EXCHANGES	2
Monitor mailings	<u>7</u>
T O T A L	<u>27</u>

Response to PID Issues raised in 81 State 189888

- Research: Research should support project's other two components, while being technologically innovative and not duplicative where advances already made elsewhere.

Research plans developed for this project were carefully prepared with the assistance of some of the foremost authorities in the field of reproductive immunology. Research activities will draw on advances made elsewhere whenever appropriate and will adapt such advances to the conditions in India.

PROJECT DESIGN SUMMARY
LOGICAL FRAMEWORK

Project Title and Number Family Planning Communications and Marketing; 386-0485

<u>Narrative Summary</u>	<u>Objectively Verifiable Indicators</u>
<u>Goal:</u> Reduce fertility of young married couples and rate of population growth	Reduction in the net reproduction rate from 1.67 to 1.4 by PACD.
Purpose: Increase use of safe, readily available, inexpensive, non-terminal methods of fertility regulation.	Prevalance of temporary contraceptive increased from 6% of eligible couples to 20% of eligible couples by PACD.
Outputs: Semi-autonomous, non-profit society to promote interests of contraceptive producers and marketers, and consumers.	Contraceptive Marketing Organization with one central office and five regional offices in place and functioning.
Strengthened GOI Information Education, Communication Program.	12 communications specialists and 100 trainers trained; 5000 extension educators retrained; 2 mass media programs launched per year.
Improved capability to analyze demographic data and social and economic factors related to mortality and fertility.	Results of research by Registrar General and U.S. institutions published; individuals trained in statistical sampling, computer data systems, and demographic analysis;
Improved capability to conduct bio-medical research.	4 Indian Institutions involved in collaborative biomedical research with U.S. institutions.
<u>Inputs:</u> Support to development of Contraceptive Marketing Organization (CMO).	\$6.00 million expended to support administrative cost of CMO.
Support for promotion and advertising of contraceptives.	\$25.5 million expended to finance promotion and advertising.
Training in IEC	5000 workers participate in training courses/seminars; 200,000 registered private practitioners exposed to information on reversible family planning measures.
Indo-U.S. collaboration in demographic and bio-medical research.	Indo-U.S. collaboration takes place.

Means of Verification	Assumptions
Decennial Census; Sample Registration System; Contraceptive Prevalence Surveys, IRHP Surveys	Increasing proportion of Indian couples will desire more delay and spacing of pregnancies.
Distributor Information; Commodity Movement Records from GOI Program; Contraceptive Prevalence Surveys.	Public and Private sector IEC promotion campaigns will be adequate to increase demand for fertility regulation systems will exist.
Articles/Memorandum of Association central and regional offices and staff; data and prescribed reports.	GOI will establish autonomous marketing organization for fertility regulation; GOI will recruit staff at levels of emoluments sufficient to attract high executive talent.
Reports from Training Institutes certified by Ministry of Health and Family Welfare field visits.	GOI task force on communications strategy will be active throughout project life.
Reports and Publications from ICMR, Dept. of Science and Technology, Planning Commission, RG/Census Commission and population institutes.	Staff will be available for collaborative activities; mutually beneficial relationships between U.S. and India institutions will be established.
USAID Financial Records; GOI Financial Records; Marketing Organization Financial Records.	U.S. and GOI proposed funding levels and project design are approved by the respective governments and expenditures proceed on a timely basis.

Preliminary Calendar of Project Events

- | | |
|----------------|--|
| July, 1983 | - Project Agreement signed |
| August, 1983 | - U.S. biomedical contractor confirmed (PARFR);
- Visit to India; Indian participant in U.S. Task Force selected |
| October, 1983 | - A.I.D. Contract with PARFR amended to provide support to key U.S. institutions for Indo-U.S. collaboration |
| November, 1983 | - U.S. Task Force on Immunology of Reproduction convened in U.S.
- Indian specialist visits U.S. labs/vice versa |
| January, 1984 | - Immunology proposals reviewed by Task Force members
- U.S. Task Force Second Meeting |
| February, 1984 | - PARFR awards 2 to 3 sub-contracts to U.S. Institutions |
| March, 1984 | - Transfer of Cryo-preservation technology |
| April, 1984 | - Selected materials exchanged between Indian and U.S. laboratories |
| June, 1984 | - Indian specialists visit U.S. labs/vice versa
- PARFR awards 2 to 3 final subcontracts to U.S. institutions |
| August, 1984 | - Joint Report by Institute of Immunology and PARFR to GOI/Dept. of Science and Technology and to USAID on progress and plans for year 2 |
| October, 1984 | - Third Meeting of U.S. Task Force on Immunology
- Review of future needs (if any) for further bilateral support |
| November, 1985 | - Fourth Meeting of U.S. Task Force on Immunology |
| December, 1985 | - Distribution of Research Reports |

BUDGET ESTIMATES FOR BIOMEDICAL RESEARCH

A. Supplies of Materials (E.G. Radioisotopes)	\$75,000/yr x 5	=	375,000
B. Task Force	28,000/yr x 2	=	56,000
C. Cryopreservation			10,000
d. Targeted Studies	(E.G. 3 x 186,000)	=	<u>559,000</u>
			<u>\$1,000,000</u> -----

DEC 26 1984

ACTION MEMORANDUM FOR THE ASSISTANT ADMINISTRATOR, BUREAU FOR ASIA

FROM: ASIA/PD, Robert Pratt *R. Pratt*

SUBJECT: India - Request for Project Approval at Mission

Problem: To approve authorization by USAID/New Delhi of a new project, Contraceptive Development: Reproductive Immunology (386-0500) based on design work contained in an earlier family planning project. Life-of-project funding would be \$1 million in grant money (\$100,000-Health, \$900,000-Population), all to be obligated in FY 1985.

Background: In FY 1983, the Family Planning Communications and Marketing (FPCM) project was authorized by the Acting Administrator for \$48 million (\$14 million grant, \$34 million loan). At that time, a reproductive immunology component was included. Subsequently, the Government of India (GOI) requested the component be removed from the project to allow for further GOI review. As a result, a project authorization amendment deleted this particular component from the project (Attachment C). The Administrator was informed in the accompanying Action Memorandum supporting this amendment that the component would be processed as a separate project or part of some other project in the future.

Upon further consideration, the GOI requested A.I.D. to proceed with the reproductive immunology activity as a separate project. USAID/New Delhi asks your approval, therefore, to authorize a "new" project identical to the reproductive immunology component described in the FPCM project paper. The Mission is prepared to obligate funds very quickly upon submission and clearance of a Congressional Notification (CN) to Congress. ASIA/PD will prepare the CN as soon as the appropriate information is received from the Mission.

Justification: The Mission indicates no substantive changes in the component as outlined in the original PID and Project Paper are contemplated. Since AID/W approved the FPCM project including this particular component, USAID/New Delhi believes no new PID nor PP review is necessary. ASIA/PD concurs.

The reasons for creating a new project for this activity relate to GOI administrative and budgetary problems. As outlined in the Mission cable (Attachment B), the FPCM project falls under the jurisdiction of the Ministry of Health and Family Welfare, whereas the reproductive immunology component falls under a separate entity.

14

the Department of Science and Technology. These entities receive separate GOI budgetary allocations, and project funds will flow much more smoothly if project responsibilities are kept separate. Both the Mission and GOI prefer creation of a discrete project.

Recommendation: That you concur with USAID/New Delhi's request to authorize the Contraceptive Development: Reproductive Immunology Project (386-0500) by signing the attached cable (Attachment A).

Approve *ILT*

Disapprove / /

Charles W. Greenleaf

Charles W. Greenleaf
Assistant Administrator

Dec 28, 1984

Date

Attachments: a/s
FPCM PP (with relevant section marked)

Clearance:

DAA/ASIA:ESStaples		Date
ASIA/DP:JWestley	(draft)	Date 12/27/84
ASIA/BI:JManley	(draft)	Date 12/27/84
ASIA/PD:DDevin	(draft)	Date 12/27/84
ASIA/PD:PMatheson	(draft)	
GC/ASIA:HMorris	(draft)	
ASIA/DP:LCrandall	(draft)	
PPC/PB:LLeDuc	(draft)	
ASIA/TR:DOot	(draft)	
ASIA/PD:SBUGG	(draft)	
S&T/POP:CCromer	(draft)	

Draft:AID/ASIA/PD:EKvitashvili:12/28/84:29000:#3180k

ACTION OFFICE POP-04
INFO ASPH-02 FM-02 A-PO-01 ASTR-0: STHE-01 JACT-01 RELO-01
STHP-01 MAST-01 ASB-0: /020 AA 313

INFO OCT-00 COPY-01 OES-09 /010 V

-----342765 1310122 /13/12/38

P 130759Z NOV 84
FM AMEMBASSY NEW DELHI
TO SECSTATE WASHDC PRIORITY 7769
INFO AMEMBASSY ISLAMABAD

UNCLAS NEW DELHI 25097

AIDAC

ISLAMABAD FOR RL4

E.O. 12366 N/A
SUBJECT: POPULATION: FAMILY PLANNING COMMUNICATIONS AND
MARKETING PROJECT (386-11485) REPRODUCTIVE IMMUNOLOGY
COMPONENT

REF: (A) PROJECT AUTHORIZATION (B) ACTION MEMORANDUM FOR
THE ACTING ADMINISTRATOR DATED AUGUST 25, 1983

1. GOI HAS INFORMED US THEY WISH TO PROCEED WITH
AGREEMENT ON THE REPRODUCTIVE IMMUNOLOGY COMPONENT OF
THIS PROJECT AS QUICKLY AS POSSIBLE. A PROCEDURAL
PROBLEM HAS ARISEN, HOWEVER, TO WHICH A SOLUTION IS
PROPOSED BELOW.
ACTION REQUESTED - AID/V CONCURRENCE.

2. AID/V MAY RECALL THAT ALTHOUGH THIS REPRODUCTIVE
IMMUNOLOGY COMPONENT WAS BUILT INTO THE PROJECT PAPER
AND AUTHORIZED BY AID/V DURING FINAL NEGOTIATION GOI
REQUESTED ITS DELETION FROM THE PROJECT AGREEMENT TO
ALLOW FOR FURTHER REVIEW OF THIS SUBJECT. AS A RESULT
THE COMPONENT WAS DELETED FROM THE ORIGINAL
AUTHORIZATION BY PROJECT AUTHORIZATION AMENDMENT DATED
AUGUST 25, 1983.

3. REASON FOR THE GOI REQUEST WAS THE FACT THAT THIS
RESEARCH COMPONENT FALLS UNDER THE PURVIEW OF THE
DEPARTMENT OF SCIENCE AND TECHNOLOGY (DST), WHEREAS THE
REST OF THE PROJECT (WITH THE EXCEPTION OF THE
DEMOGRAPHIC ANALYSIS COMPONENT) IS THE RESPONSIBILITY OF
THE MINISTRY OF HEALTH AND FAMILY WELFARE. DST HAD,
APPARENTLY THROUGH OVERSIGHT, NOT BEEN BROUGHT INTO THE
CLEARANCE PROCESS BY THE GOI EVEN THOUGH THIS COMPONENT
HAD BEEN DISCUSSED IN DETAIL WITH USAID DURING
DEVELOPMENT OF PROJECT.

4. A GOI HAS ALSO EXPLAINED A PROCEDURAL PROBLEM THEY
HAVE IN COMBINING THIS COMPONENT WITH THE REST OF THE
PROJECT. IN THIS SYSTEM EACH PROJECT GENERALLY FALLS IN
TOTAL INTO THE DEVELOPMENT BUDGET OF ONE MINISTRY OR
ANOTHER. IT IS VERY DIFFICULT, AT LEAST IN THE SHORT
RUN, TO SPLIT A USAID PROJECT BETWEEN MINISTERIAL
BUDGETS, AS WE HAVE DISCOVERED WITH THE CLEARANCE OF THE
DEMOGRAPHIC ANALYSIS COMPONENT. AS A RESULT, EVEN
THOUGH THE GOI NOW WISHES TO PROCEED WITH THIS ACTIVITY,
THEY DO NOT WANT THIS COMPONENT TO BE AN ADDENDUM TO THE
FAMILY PLANNING COMMUNICATIONS AND MARKETING PROJECT,
WHICH BELONGS IN THE MAIN TO THE MINISTRY OF HEALTH AND
FAMILY WELFARE. THEY WANT THE PROJECT COMPONENT TO BE
REGARDED AS A DISCRETE ENTITY UNTO ITSELF UNDER DST.

5. DOING SO COULD COMPLICATE WORK ON OUR SIDE, BECAUSE

NORMALLY A SEPARATE PROJECT REQUIRES A SEPARATE PID AND
SEPARATE PP. HOWEVER, THE FPCM PROJECT PAPER DESCRIBED
THIS COMPONENT AND, ON THE STRENGTH OF THAT PP, THE
COMPONENT WAS ORIGINALLY AUTHORIZED AND WOULD HAVE GONE
FORWARD HAD WE NOT AT THE LAST MOMENT REQUESTED ITS
DELETION. WE THEREFORE PROPOSE THAT THE ORIGINAL PID
AND PERTINENT SECTIONS OF THE SUBJECT PROJECT PP SERVE
AS THE BASIS FOR USAID/INDIA'S MISSION DIRECTOR
AUTHORIZING A NEW REPEAT NEW PROJECT WHICH WOULD BE
IDENTICAL TO THE REPRODUCTIVE IMMUNOLOGY COMPONENT
DESCRIBED IN FPCM PROJECT PAPER ON BASIS OF THIS
AUTHORIZATION WE WOULD SIGN A NEW PROJECT AGREEMENT
ENTITLED "CONTRACEPTIVE DEVELOPMENT: REPRODUCTIVE
IMMUNOLOGY" FOR WHICH THE LINE MINISTRY -- AND THUS THE
BUDGET HOME -- WOULD BE THE DEPARTMENT OF SCIENCE AND
TECHNOLOGY.

6. IF AID/V CONCURS IN THIS APPROACH, USAID AND GOI CAN
BE PREPARED TO OBLIGATE DOLLARS ONE MILLION IN
POPULATION FUNDS FOR THIS ACTIVITY AS SOON AS FUNDS
ALLOTTED AND CM IS CLEARED.

7. THE WHOLE POINT OF THIS PROPOSAL IS TO HELP THE GOI
GET AROUND A VEXING BUREAUCRATIC, BUT REAL PROCEDURAL
PROBLEM. ALL PARTIES ARE KEEN TO PROCEED WITH THIS
COMPONENT; NO REPEAT NO SUBSTANTIVE CHANGE FROM THAT
PROPOSED IN PP IS CONTEMPLATED ON EITHER SIDE.
MOREOVER, WE BELIEVE A NEW AND SEPARATE PROJECT WILL RUN
CONSIDERABLY MORE SMOOTHLY BECAUSE PROJECT FUNDS WILL
NOT BE FORCED TO BE CHANNELLED THROUGH THE BUDGET OF THE
MINISTRY OF HEALTH AND FAMILY WELFARE. FURTHERMORE, WE
SEE NO NEED TO BURDEN AID/V WITH APPROVAL PROCESS FOR
THIS SMALL COMPONENT BECAUSE AID/V HAS REVIEWED AND
APPROVED IT ALREADY DURING THE INITIAL AUTHORIZATION
STAGE. WE THINK, THEREFORE, THE MOST EXPEDIENT SOLUTION

WOULD BE FOR USAID/I TO AUTHORIZE A SEPARATE PROJECT
USING ORIGINAL PID AS THE BASIS FOR PROCEEDING, AND
USING FPCM PROJECT PAPER SECTIONS DESCRIBING THIS
COMPONENT AS BASIS FOR MISSION DIRECTOR'S AUTHORIZATION.
(PP, PAGES 6, 22, 23, 26, 27, 33, 35, 36, 63, 72, 149,
164).

8. PLEASE ADVISE CONCURRENCE. CM DATA SHEET FOLLOWS
SEPT.EL.BARNES

1 L 1. E
AUG 25 1983

MEMORANDUM FOR THE ACTING ADMINISTRATOR

TO: A/AA/FPC, Richard A. Derham *RD*

FROM: AA/ASIA, Charles W. Greenleaf, Jr.

SUBJECT: INDIA - Family Planning Communications and Marketing Project (386-0485), Request To Amend Project Authorization and Approve Changes to Conditions Precedent

Problem: You are requested to amend the Project Authorization to delete a \$1 million component for biomedical research on reproductive immunology and approve proposed changes to conditions precedent in the Project Agreement for the Indian Family Planning Communications and Marketing Project (386-0485).

Discussion: The subject project was authorized on July 27, 1983. The authorization provided financing of \$34.0 million in loan funds and \$14.0 million in grant funds. The project is designed to assist the Government of India (GOI) to increase fertility awareness and the use of safe, readily available and inexpensive, temporary methods of contraception.

1. Biomedical Research

The GOI has requested deletion of the component of the project providing support for biomedical research on reproductive immunology. This small component is not integral to the project and was added originally at the request of the GOI.

Deletion of this component is not the result of lack of interest in biomedical research by the GOI. USAID has submitted a PID for a Biomedical Support for Health Services Project that will commence in FY 1984. Rather, the deletion of biomedical research from the Family Planning Communications and Marketing Project was requested because the GOI has not yet finalized its policy on biomedical research. As a result, GOI clearance of this component, budgeted at \$1.0 million in the subject project, would delay the entire project. To avoid this delay, the GOI has proposed that it be processed as a separate project or included in some future project.

We believe this component may be deleted from the project without adversely affecting the other components or achievement of the primary objectives of the project and we recommend that you approve this request. The total amount of assistance and the amount of grant funding provided in the project also will be reduced in the amount of \$1.0 million.

Precedent to Disbursement

GOI has requested a change in the conditions precedent which requires selection and appointment of the board of directors, executive director and all of the product managers, in consultation with A.I.D., prior to disbursement for the Contraceptive Marketing Organization (CMO). The purpose of this condition is to ensure a satisfactory mix between members from the public and private sectors for the board of directors and chief operating offices of the CMO in an effort to enhance its ability to operate more effectively using essentially private sector techniques.

The GOI has raised two concerns regarding this condition. First, the GOI believes it is not necessary to have all the product managers selected and appointed in order for the CMO to commence operations and satisfy the condition precedent. Second, consultation with a foreign government in selection and appointment of personnel for an indigenous organization is a sensitive issue and should not be required in a formal bilateral agreement. However, the GOI agrees "without hesitation" to consultation and has indicated that consultation could be covered in an exchange of letters.

USAID believes the GOI concerns are reasonable and recommends acceptance of the GOI requested change in the conditions precedent permitting an adequate number of product managers selected and appointed in order for the CMO to commence operations and consultation in the selection and appointment of CMO board of directors, executive director and product managers through an exchange of letters. In our view, consultation regarding personnel of the CMO is the more significant feature, and we find an exchange of letters regarding consultation to be satisfactory.

The GOI also has requested that another condition precedent be clarified in a minor, technical way. Prior to AID's making a disbursement for the CMO, the GOI must provide evidence that the CMO has been provided adequate funding to cover all procurement to be undertaken by the CMO during its first year of operation, including the procurement of contraceptives for the social marketing and free distribution programs.

The CMO may not take over responsibility for the free distribution program until late in the first year or the second year of the project. In that case, it would make no sense to require full funding for that program prior to A.I.D.'s first disbursement to the CMO. The GOI has requested a clarification to this condition by the addition of the words "as undertaken by the CMO during that year". This change is acceptable; it merely reflects what was always intended as a condition to A.I.D.'s first disbursement.

These conditions precedent were not included in the Project Authorization and may be approved, therefore, without amendment of the Authorization in this respect.

The AA/ASIA has approved certain clarifying modifications to standard provisions of the Project Agreement and its annex requested by the GOI and recommended by USAID/New Delhi.

Recommendation: That you sign the attached Project Authorization Amendment reducing the amount of grant funding available for the project by \$1 million and deleting the biomedical research component and approve the modifications to the conditions precedent to disbursement as described above.

Approved /s/Frank B. Kimball

Disapproved _____

Date 8/25/83

Clearances:
GC:RADerham YAM Date 8/25/83
PPC/PDPR:ELHullander B Date 8/22/83

Attachment:
Project Authorization Amendment

ASIA/PD/SA:GMImhoff:rcs:8/25/83:X29000

- Clearances:
- A/ASIA/PD:RPratt (draft)
 - ASIA/TR:RSimpson (draft)
 - GC/ASIA:STisa (draft)
 - ASIA/DP:LSmucker (draft)
 - ASIA/PD/SA:HRSharlach (draft)
 - ASIA/BI:GCarner (draft)
 - S&T/POP:JSpeidel (draft)

PROJECT AUTHORIZATION

AMENDMENT

INDIA

Family Planning
Communications
and Marketing
Project No. JRA-0485

1. Pursuant to Section 104(b) of the Foreign Assistance Act of 1961, as amended, the Family Planning Communications and Marketing Project for the Government of India was authorized on July 27, 1989. That authorization is hereby amended to reduce the amount of grant funds available for the project by \$1,000,000 from \$14,000,000 to \$13,000,000 and to delete the biomedical research component of the project.

2. The authorization cited above remains in force except as hereby amended.

Signature /s/ Frank B. Kimball
W. Peter McPherson
Administrator

8/25/89

DATE

Clearances:

Date

Initial

Charles W. Greenleaf, AA/ASTA 8/25/89 CGW

Richard A. Dethan, A/AA/PRC 8/25/89 RAD

Richard A. Dethan, A/OC 8/25/89 RAD

A/ASIA/PD: RPratt 8/25/89 RPR

ASIA/DP: LSnucker 8/25/89 LSN

ASIA/BI: RBeckman 8/25/89 RBE

CC/ASIA: STisa:hd/el:8/25/89:27367

20

accelerate analyses of age-specific fertility and other parameters necessary to evaluate the impact of the GOI program and of this project, and help identify key target groups. A total of \$1.1 million is budgeted for this component to support U.S. costs for collaboration and training.

5. Biomedical Research

The project will support Indo-U.S. collaboration in biomedical research, especially in reproductive immunology. This small but important component will help India continue the search for better and more appropriate fertility regulation methods, and will capitalize on India's unique capabilities in this field. New methods of fertility regulation will increase choices for couples in India and elsewhere, and may provide a "safety net" if current program methods fall short. The budget for this component is \$1 million to cover costs in the U.S. for materials, workshops and studies.

F Background and Rationale

1. GOI Population Policy, Plans and Targets

In 1952 India became the first country to adopt an explicit policy to reduce population growth. Since then many leaders, Cabinet and Parliamentary resolutions, and official commissions have endorsed various voluntary measures. Over the years, ambitious goals for lowered birth rates have been set and subsequently have had to be reduced.

A GOI program has been the main policy vehicle with targets for specific methods. There appears always to have been an implicit assumption that this program must do the full job. The Sixth Five Year Plan originally projected 22 million sterilizations, 7.9 million IUD insertions and 11 million "equivalent" users of conventional contraceptives (mostly condoms, but also including oral contraceptives) between April, 1980 and March, 1985. The Sixth Plan envisaged an increase from 23 percent of couples effectively protected through the official program (as distinct from private sector sales) in 1979/80 to 36.5 percent in 1985/86, and to 60 percent by 1995/96^{1/}, thereby reaching replacement level fertility.

Probably no more than twenty-five percent of Indian reproductive age couples have been using effective methods in any year since 1979. Perhaps an additional ten to fifteen percent may be assumed to be infertile or subfecund at any time. A major increase in the range and acceptability of contraceptives will be required to increase prevalence by an additional 35% percentage points in only 14 years and to reach 34.5% by 1986 will require great effort.

^{1/}GOI definition of couples "effectively protected" is arrived at by multiplying the couples currently protected by estimated use effectiveness of the method, which is taken by GOI as 100% for sterilization and orals, 95% for IUDs and 50% for condom and other related barrier methods.

d Biomedical Collaboration

Biomedical collaboration will be undertaken as coordinated investigations between leading Indian and U.S. institutions based on the mutual interests of Indian and U.S. institutes and of individual scientists, particularly in the field of immunology of reproduction. This will include investigators in India from the Indian National Institute of Immunology, the Post Graduate Institute of Medicine at Chandigarh, the Institute for Research and Reproduction at Bombay, the Indian Institute of Science at Bangalore, the Central Drug Research Institute at Lucknow; and in the U.S., investigators at the Department of Biochemistry and Molecular and Cell Biology, Northwestern University, Oregon Primate Center, the International Committee for Contraceptive Research (Population Council) and at the National Institute of Health, Bethesda, Maryland, among others.

Immunological approaches to human fertility regulation are now feasible based on recent biological advances and the new technologies of human mono-clonal antibody production and genetic engineering. Indo-U.S. collaboration already exists between the Indian Institute of Immunology and International Committee for Contraceptive Research focusing on post-fertilization techniques.

This project will support research only on pre-fertilization methods. Because of strong Indian resources, expertise and interest in this specific research area and because of the recent advances in the U.S. in the field of reproductive immunology (especially in the area of andrology), two complementary approaches will be taken. Both involve support to U.S. institutions to sustain U.S. costs of collaboration in India and dollar costs of Indian participation in the joint program. The first will involve a U.S. Task Force with participation of Indian scientists and the second will involve targeted research projects. The Task Force will convene to prepare workscopes for U.S. contractors and studies to be undertaken with the GOI Department of Science and Technology (DST). This Task Force will determine the topics to be studied. AID/ST/POP, USAID/New Delhi and representatives of the GOI/DST will select an appropriate U.S. institution to serve as prime contractor and convener of the U.S. Task Force. Due to their apparent predominant experience this seems likely to be the Program for Applied Research in Fertility Regulation (PARFR) at Northwestern University, Evanston, Illinois. Likely topics for targeted research are as follows. The

first concerns a sperm-specific antigen which has been successfully used to immunize mice, rabbits and baboons against pregnancy. Studies may be supported to test its antigenicity with synthetic adjuvants in monkeys, to test the minimum antibody needed via passive immunization to prevent fertility, and finally to see if this specific antigen can be produced synthetically.

The second targeted research may study specific sperm antigens previously identified through the study of sera of infertile couples. Passive immunization studies will be conducted to determine titers necessary to prevent fertility. Subsequently conjugation of specific antigens may be undertaken for active immunization.

The third targeted research may be directed towards an antigen contained in the zona pellucida surrounding the egg. Studies are needed to define the antigen biochemically, and this leads into the fourth targeted area of immunopathology studies. These safety studies will most appropriately be carried out at different Indian institutions with special arrangements for pathological studies.

The fifth targeted area will transfer the technology of cryopreservation of sperm and of antigens. This will have both veterinary value as well as importance for human egg and sperm preservation.

New computer simulation techniques developed in the U.S. may become the subject of joint studies and technology transfer.

Finally, and perhaps most promising, this project will study the effectiveness of the IgA secretory antibodies in cervical mucous, which, if effectively demonstrated, will lead to monoclonal IgA antibody production for bonnet monkeys -- a major step towards development of the technology for humans.

It is anticipated that the several Indian institutes with scientists and laboratories working on reproductive immunology, members of which make up a complementary Indian Task Force, will communicate freely with U.S. reproductive immunologists and the NIH for long range research planning. The task force approach in reproductive immunology has been singled out for emphasis by the Indo-U.S. Senior Scientific Panel at the February 1983 meeting in New Delhi.

5. Inputs

a. GOI

- the establishment of and provision of funds for the CMO and the transfer to it of responsibility for social marketing and central management of free distribution of contraceptives;

POP

NATIONAL INSTITUTE OF IMMUNOLOGY

Title : Support for a joint Indo-US Collaborative programme in contraceptive development.

Duration : 36 Months

Sector : Govt Class : Science & Technology

Sub-sector : Govt. Class : Disease prevention
USAID-386-0485- Family Planning Communication & Marketing Project.

Govt. Implementing Agency : Department of Science & Technology through National Institute of Immunology.

Govt Inputs :

Foreign Sponsor/Donor Inputs : US \$ 1,000,000

DRAFT
DEC 84

SUMMARY OF THE PROJECT PROPOSED

1. Title of the Project : Development Studies in Reproductive Immunology.
2. Field of Study : Contraceptive research in certain non-controversial areas.
3. Specific Topic of Study in the field : Research in
1) Sperm antigens
ii) Ovum Specific antigens.
iii) Molecular biology approach for cloning and expression of gametes.
4. Administrative Ministry concerned : Department of Science & Technology.
5. Funds proposed to be found from foreign sources and phasing of funds over project life :

\$ 500,000	1st Year
\$ 250,000	2nd Year
\$ 250,000	3rd Year
6. Sources of Foreign Funds: U.S. Agency for International Development
7. Brief description of Project & its necessity and relevance : The Project is to support a programme in contraceptive research in certain non-controversial areas. In particular the grant will focus on i) Sperm antigens, ii) Egg-antigens ; and iii) Molecular biology approach for cloning and expression of gametes. The previous work has primarily been found to be vaccine directed against hCG, which is currently receiving national (NCF) and international (IDRC) funding. The USAID grant is to help

enlarge our interest on additional vaccines which could play a symbiotic role and which may be useful eventually in a polyvalent approach.

8. Benefits expected to
accrue

a) Sperm antigen : The last characterized sperm antigen at molecular level is LDH-C₄. The work has been primarily carried out by E. Goldberg in Chicago. The enzymes have been purified and its primary sequence elucidated. Sub-fragments of this antigen reacting with antibodies have also been identified. Preliminary data is available with them in the reduction but not complete block of fertility in rabbits, mice, in rats, and in baboons immunized with this antigen. The immunization carried by FCA is non permissible for eventual human use. This group would like to benefit from our experience in making this antigen immunogenic with carrier and other permissible antigens. In return we will have access to antigen and freedom to use it in a polyvalent antigen. Research in US is in progress to identify the potentially protective antigen. Several US Scientists including some Indians settled in USA, viz Dr. RK Naz have developed monoclonal antibodies against sperm antigens. In our own laboratory preliminary work has given rise to generation of several clones which can immobilise the Sperm. Exchange of information and cross check of various antibodies by investigation in the two countries could lead to saving of time and will add to speed of progress in this area.

b) Egg antigens : The antizona pellucida vaccines are under development in USA and India. The project will speed up the progress in the purification of Zona pellucida antigens, identification of initial molecules imparting protection without side effects.

c) In view of scarcity of the source material for obtaining egg or Sperm antigen it is imperative to resort to Cloning of genes

and their expression in suitable system. The training and transfer of technology connected with this programme will be beneficial to the project under review as well as to other projects of utility.

Other benefits that will accrue are :

- d) Acquisition of latest and sophisticated equipments/instruments against dollar payments.
- e) Publication of research results for furtherance of the work and for benefit of research in the field.

Part II-A

DEVELOPMENT OBJECTIVES

The development objective of the project is to contribute to health development plans to improve upon the health conditions of the population in India and elsewhere with the development of contraceptive vaccines which could play a symbiotic role and which may be useful eventually in a polyvalent approach. It will contribute to the TCDC in the production of new and potent vaccines as well as training of the young Indian Scientists abroad in the requisite techniques. The mandate of the Institution approved by the Governing Body provides, inter alia, to carry out research for development of new contraceptive vaccines, and immunological approaches for control of reproduction, to collaborate with foreign research institutions and laboratories and other international organizations in field relevant to the objectives of the Institution.

The achievement of the objective would emerge from the combining of the researches already done by the two countries and augmenting the efforts.

Part II-B

IMMEDIATE OBJECTIVES

i) Development of contraceptive in certain non controversial areas. The areas encompass the development through newly emerging immunologic techniques of contraceptive vaccines directed against either Sperm or non fertilized eggs.

ii) Technology transfer from laboratory fields of application by creating infrastructure for development of technology.

Part II-C

BACKGROUND AND JUSTIFICATION

The National Planning Commission has identified

20

immunology, an important multi-disciplinary area of life sciences as research for thrust support. The Government appointed a high powered technical and inter-ministerial committee in 1981 to examine the feasibility of establishing a National Institute of Immunology. The Committee surveyed the work done in this area in the country. The Committee noticed the tasks and achievements of Research and Training in Immunology at the All India Institute of Medical Sciences, operating since 1973 with the assistance of WHO and ICMR. The Centre has been organizing teaching and laboratory courses in Immunology for India and South East Asia Region, conducting research on problems of relevance to India. This Centre did valuable work in the field of Immunology. However, the Centre did not have adequate facility for R and D and technology development. On the recommendations of the technical and interministerial committee, the Government of India decided to develop this Centre into a National Institute under the Department of Science and Technology which is the apex body on Science & Technology development and research in the country. The Institute came into being as a Registered Society in 1981, with the following tasks/objectives assigned to it :

- a) To undertake, aid, promote, guide and coordinate research of a high calibre in basic and applied immunology ;
- b) To provide and promote effective linkages on a continuing basis between various scientific and research agencies/laboratories and other organization working in the country in the field of immunology, vaccine development and related areas ;
- c) To organize post-graduate courses, workshops, seminars symposia and training programmes of a specialized nature in the field of immunology, vaccine development and related areas ;

- d) To organize training programmes for technicians in immunological methods and related techniques.
- e) To serve as a National Reference Centre for Immunology and to provide consultancy services to medical and veterinary institutions, public health agencies and industry in the country ;
- f) To carry out research for development of new vaccines and immunological reagents for communicable diseases ; as also for improvement of the currently available vaccines with deficient immunological properties ;
- g) To develop immunological approaches for control and promotion of male and female fertility.
- h) To interact with industry for manufacture of vaccines and immunological reagents ;
- i) To collaborate with foreign research institutions and laboratories and other international organizations in field relevant to the objectives of the Institute ;
- j) To establish affiliation with recognized universities and institutions of higher learning for the purpose of enabling research scholars to register for post-graduate degrees.

The focal themes of research at the Institute to achieve these objectives are on high priority problems of relevance to human and animal health in the country. These programmes are to be built on an existing base, from where important leads have been generated.

The Institute was constituted to provide a working base for high calibre basic and applied research in this important multidisciplinary area of Life Sciences for which adequate

facilities of a comprehensive nature are not available in the country. This task demands setting up of properly equipped laboratories covering various facets of the discipline, as well as bringing together of scientists with appropriate formation to achieve a critical mass.

The Institute is designed to serve as a Centre for training and manpower development. This function will be fulfilled by running of specialized courses and workshop for teachers and investigators in other Institutions, by provision of 'in residence' training in methods and other areas to sponsored candidates. The Institute would also provide training and facilities for research leading to Ph.D degree. It will have academic affiliation with universities and institutions of higher learning in Life Sciences, Medical and Engineering Sciences. It has been recognized as a Research & Training Centre in Immunology by the World Health Organization for India and South East Asia.

The Institute would act as a National Reference Centre in Immunology. Amongst the many functions to be performed under this head would be the supply of standardized reagents. The technicians training programme will have the aim of fostering capability for preparing mono-specific antisera and other reagents locally leading to self reliance.

During the short span of three years or so, the Institute has done valuable work and made research contributions some of which may be mentioned here :

- a) One of the Hybridoma clones developed by the Institute which makes anti-hCG antibodies, was acquired by a leading firm in USA for incorporation into an array of products. The choice of this clone in this highly

....8/-

competitive field was based on distinctly superior merits of the clone. The product using these antibodies was approved by the Federal Authorities in USA and was introduced in the market in March 83.

- b) Four different laboratories have confirmed the efficacy of our first vaccine based on B-hCG in the anti-gonadotropin vaccine field.
- c) Two methods were successfully developed for sensitive detection of hCG and diagnosis of early pregnancy and hCG synthesizing tumours. These kits are now under arrangements for commercial production and distribution by an Indian Company.
- d) The work done on antifertility vaccine so far carried out was reviewed by a team of eminent experts of international agency like IDRC of Canada. The team commended the work done by the Institute.

In 1982/83 a project entitled " Family Planning Communications and Marketing" was designed by USAID and the Govt. of India. One of the discrete components included in the project was support for a programme in certain non-controversial areas that the designers felt offered good chances for contributing to the achievement of the project's overall objectives. The designers also felt that the Collaboration between leading American and Indian Scientists in these areas was essential for progress. Para 8 of Part-I clearly brings out the justification and how the project is expected to make an effective contribution towards realising the objective.

...9/-

1/2

Part-II-DOUTPUTS

Upon completion of the Project, the following specific outputs would be available : Reports on :

- 1) Research on the gamete antigens (Sperm and egg antigens). The collaborative work envisages combining of the two experiences to evolve a workable vaccine directed against this antigen.
- 2) A parallel line of research on development of a vaccine at DNA level combining immunoprophylaxis and fertility control is proposed.
- 3) Phase wise purification of zona pellucida antigens identification of initial molecules imparting protein without side effects and eventually development of antizona pellucida vaccines.
- 4) Reports on diffusion and dissemination of information for transfer of technologies to other institutes as well as industry.

Part II-EACTIVITIES

Two Committees will be responsible for planning and scientific oversight of the programme. A clearance Committee will be responsible to respective government authorities for obtaining approval and clearances. The Committee may be bilaterally constituted and chaired by a representative from the DST. Other members of the Committee should be drawn from the ICMR, Min. of Health & Family Welfare, and NII on the Indian site, and N.I.H., the population office of the AID

...10/-

In Washington, the Population office of the local USAID mission. The technical advisory Committee will be responsible for defining needs and approving protocols and budgets. Membership of this Committee will be determined by the Clearance Committee with the approval of the DST. It is recommended that the N.I.I., AIIMS, NIHFW, ICMR, DST, CDRI in India and NIH, AID/Washington, and Collaborating Institutions in US, as appropriate, be represented on the Technical Advisory Committee.

{ NOTE : The above mode of management of the Project has been }
{ decided in consultation with DST, ICMR, NII & USAID. }

LOCATION : National Institute of Immunology, New Delhi

Starting dated and : March 1985
Proposed Duration : 36 Months

Part-II-F

INPUTS

1) GOVERNMENT INPUTS

- a) Assignment of National Staff : The Director N.I.I. will perform the duties of Project Director and will be assisted in his work by Core Scientist. Other specific staff requirements will be met from Foreign Agency Inputs.
- b) Government provided buildings, supplies, equipment and other physical facilities : The Buildings and other physical facilities of the Institute are being built in the Jawaharlal Nehru University Complex. The first phase of the activities will be completed by March 1985 and the Institute, now located partly at AIIMS and partly in a hired building will shift in its own campus by March 1985. The equipment, furniture, power supply, services for laboratories like compressed air, hot water, gas, vaccum, liquid nitrogen, indigenously available

chemicals, reagents, isotopes, alcohol, a central workshop for repair/maintenance of equipments etc. will be provided by the Institute and expenditure towards these will be met from the core funds provided by the DST.

2. FOREIGN AGENCY INPUTS

US \$ 1000,000.

Details will be worked out by the Project Director in consultation with the Technical Advisory Committee (refer Part-II-E) and this will form part of Project Document.

3. Description of Foreign Sponsor/Donor Inputs

4. Foreign Sponsor/ Donor Provided Supplies & Equipments.

5. Miscellaneous.

To be finalised by the Project Director in consultation with Technical Advisory Committee; and these will form part of the Project Document.

Part II-G

PREPARATION OF WORK PLAN

A detailed work plan for implementation of the Project will be prepared by the Project Director in consultation with the Technical Advisory Committee. This will be brought forward periodically. The agreed upon work plan will be attached to the project documents as Annexure.

Part-II H

PREPARATION OF THE FRAMEWORK FOR EFFECTIVE PARTICIPATION OF NATIONAL AND INTERNATIONAL STAFF IN THE PROJECT.

The activities necessary to produce the indicated output and achieve the immediate objectives of the Project will be carried out jointly by the National and International staff assigned to it

The respective roles of the national and international staff will be determined by the Technical Advisory Committee. The framework will be attached to the Project Document as annexure and will be reviewed from time to time. The respective roles of national and international staff shall be in accordance with the established concept and specific purposes of technical cooperation.

Part II-I

DEVELOPMENT SUPPORT COMMUNICATION

Development support communication will be necessary with institutions/organisations at the afferent and efferent arc of the activities of the Institute to identify problems, provide technical solution, carryout trials of vaccines etc. Development support communication for the above purpose would be assured by regularly publishing the research result and successful technologies developed and these will be given a very wide circulation so that these are commercially taken up without loss of time and effectively consumed by the target groups of people to ensure that desired impact of the project is achieved. In this, the help of the existing media will also be obtained to the extent possible.

Part II-J

INSTITUTIONAL FRAME WORK

The Department of Science & Technology has been assigned with the principal responsibilities of promoting new areas of Science & Technology, supporting National Research Institutions and Scientific Bodies, all activities related to International S & T collaboration, coordinating multi-institutional interdisciplinary activities in areas of Science & Technology etc.

National Institute of Immunology

The National Institute of Immunology is an autonomous body under the Department of Science & Technology and it was registered as a Society in 1981 under the Societies Registration

Act XXI of 1860. The Institute is the only organization of its kind in India and South East Asia Region devoted to basic and applied research in this important and multi-disciplinary area of life sciences.

Divisions have been created for carrying our research in specific area of programmes considered and approved by the Governing Body of the Institute.

The Institute is headed by Prof. G.P. Talwar, eminent Scientist who is also head, ICMR-WHO Research & Training in Immunology for India and South East Asia from 1973 onwards ; Project leader and Member Executive International Committee on Contraception Research, Population Council, New York ; Honorary Professor of Biochemistry, All India Institute of Medical Sciences, New Delhi ; Jawaharlal Nehru Fellow 1979-81 ; Fogarty Scholar-in-Residence of National Institute of Health, USA. He has a competent team of scientists and Administrator, which is being reinforced gradually.

The majority of the scientists who have joined the Institute are scientists of Indian origin, who had extensive training and experience in reputed laboratories in USA, in most modern and up-to-date research work in the fields related to the research interests of the Institute.

Guidance/Coordination of Research Activities

The Institute has constituted an International Scientific Advisory Group composed of distinguished scientists to serve as a sort of collegium for the Institute for fulfilling the following roles :-

- 1) advise the Institute on the pros and cons of various programmes/approaches based on developments elsewhere in the world ;

- ii) foster collaborative research on projects of mutual interest ;
- iii) take in their laboratories for research, scientists from National Institute of Immunology ;
- iv) advise on scientists from abroad who could be invited for short or long term ;
- v) assist the Institute in obtaining special material ; and
- vi) be the links of the Institute with distinguished institutions in the field elsewhere in the world.

The present distinguished composition of the Group is indicated in Annexure-I.

The Institute has also constituted a Scientific Advisory Committee and Research Area Panels comprising of leading national experts in the field, to formulate programmes of research, advise on implementation of programmes, review of progress and make recommendations. The research Panel would hold discussions, in depth, in on-going research problems at the Institute. The composition of the Scientific Advisory Committee is given at Annexure II.

Collaborations : The Institute has, as on date, the following collaborative programmes :-

- 1) Indo-French Collaborative Exchange programme between Institut Pasteur, Paris and National Institute of Immunology- Under this programme the two Institutes will encourage cooperation between them by exchange of scientific and technical manpower, in carrying out research in mycobacterial diseases, immunopotential, development of new adjuvants and synthetic vaccines.

2. Indo-US Collaborative programme on ' Development of an antifertility vaccine based on immunization against LHRH in the male.
3. Collaboration with All India Institute of Medical Sciences(informal) on r-search work in basic immunology

The core funds of the Institute are provided by the Department of Science & Technology. The total funds provided is Rs. 394 lakhs for the period March 1982 to March 1985. The budget projected in the Seventh Plan period i.e. March 1985 to March 1990 is Rs. 1807 lakhs. The final allocation is awaited after the Seventh Plan is finalized. In the addition to the core funds, the Institute has a number of research grants/funds provided by other organizations. These are appended (Annexure III)

PART II-K

PRIOR OBLIGATIONS AND PRE-REQUISITES

The Government would make necessary budgetary provision and other arrangements for timely supply of counterpart inputs in staff, equipment and buildings.

The Project Document will be added through a supplement to the agreement between the Govt. of India and the US AID for the overall project entitled " Family Planning Communications & Marketing". When anticipated fulfilment of one or more of the above conditions fail to materialize USAID may, at its discretion, either suspend or terminate its assistance.

PART II-L

FUTURE SPONSOR DONOR ASSISTANCE

Final evaluation of the project is planned in Oct.1987.

Request for further involvement of USAID in the project will be submitted in due course by the Project Director and will be reviewed by the two Committees namely Clearance Committee and Technical Advisory Committee.

PART-III-A

SCHEDULE OF MONITORING, EVALUATION & REPORTS

The project will be subject to periodic reviews in accordance with established procedures by the two Committees. A mid term review will be made in 1986.

In addition, the Technical Advisory Committee will continuously monitor and review the work in project progress.

PART III-B

EVALUATION

The Project will be subject to evaluation in accordance with policies and procedures established for this purpose. The organization, terms of reference and timing of the evaluation will be decided by consultation between Govt, USAID and the Executive agency.

PART III-C

PROGRESS AND TERMINAL REPORTS

Jointly with the Executing agency, the Project Director will prepare Semi-Annual Reports and submit to the Technical Advisory Committee. A reporting schedule shall be established at the start of the Project.

The Project Director jointly with the Executing Agency will also prepare a draft Terminal Report three months before completion of the Project. The report will be submitted to the Government through the Technical Advisory Committee and clearance Committee on completion of the Project.

INTERNATIONAL SCIENTIFIC ADVISORY GROUP

Prof. Etienne Baulieu,
Hormone Research Centre & Centre
for Study of Reproduction,
Faculte de Medecine de Bicetre,
Hospital De Bicetre 94270,
Bicetre, Paris,
France.

Dr. Jonas Salk,
Founding Director,
The Salk Institute for
Biological Studies,
San Diego,
California,
U.S.A.

Dr. Barry R Bloom,
Professor and Chairman,
Albert Einstein College of Medicine,
of Yeshiva University,
Department of Microbiology and
Immunology,
New York,
U.S.A.

Prof. R.V. Short,
Medical Research Council,
MRC Reproductive Biology Unit,
Centre for Reproductive Biology,
Edinburgh,
U.K.

Dr. Melvin Cohn,
The Salk Institute for Biological
Studies,
San Diego,
California,
U.S.A.

Dr. Tore Godal,
Hydro's Institute for Cancer Research,
The Norwegian Radium Hospital,
Montebellow,
Oslo 3,
Norway.

Dr. Francois GROS,
Institut Pasteur,
28, rue du Docteur Rouse,
Paris,
France.

Prof. Fritz Melchers,
Director,
Basel Institute of Immunology,
Switzerland.

Prof. Saran Narang, F.R.C.S.,
Senior Research Officer & Adjunct Professor,
National Research Council of Canada,
Division of Biological Sciences,
Ottawa,
Canada.

SPONSORED PROJECTS/GRANTS
FUNDED BY DST/OTHER
ORGANIZATIONS- OUTLAY OF
FUNDS.

ANNEXURE - III

1.No.	Name of the Project/ Grant	Sponsoring Agency	Outlay of funds (Rs.in lakhs)	REMARKS
	Programme of Research in Immunological approach to Family Planning under the National Coordinated Task Force.	ICMR (RBFC Division)	50	Total grant of Rs.50 lakhs is spread over 3 years i.e. 1983-86. Amount spent in 1983-84 is Rs.5.84 lakhs. Balance funds to be released in 1984-85 and 1985-86 is Rs.44.16 lakhs. Grants received so far for 1984-85 is Rs.18 lakhs.
	Anti-Conceptive Technology ICCR (India) Phase-III.	International Development Research Centre (IDRC) Canada	28.6	Out of this outlay, Rs.6.53 lakhs will be spent by IDRC for internally administering the grant. Of the balance of Rs.22.07 lakhs, Rs.4.50 lakhs have been spent in 1983-84. Funds to be released is Rs.17.57 lakhs.
	Construction of Mycobacterium Leprae-DNA encoding hormones, human chorionic gonadotropin and human placental lactogen.	Department of Science and Technology	11.77	The Project was sanctioned in 1983 and is valid upto March 1985. Expenditure already made in 1983-84 is Rs.7.00 lakhs. Balance of Rs.4.77 lakhs to be made available out of which Rs.1 lakh has been released.
	Development of Hybridoma and Pregnancy Kit	Family Planning Foundation, New Delhi.	2.00	This is an open grant.
	Production of monoclonal antibodies against <u>M. leprae</u> .	ICMR	3.06	This grant is for 3 years i.e. 1984-87. Grant released for 1983-84 is Rs. 1.02 lakhs.
	Enquiry on 'Evaluation on vaccine in experimental murine models. Development of mice as a model for lepromatous leprosy.	ICMR	2.32	Grant is available upto 1985. Funds allocated for 1984-85 is Rs.0.77 lakhs.
	Enquiry on 'Development of a visual assay for <u>M.leprae</u> reacting antibodies suitable for lab. and field use.	ICMR	1.56	Grant is available upto July 1985. Funds allocated for 1984-85 is Rs.0.52 lakhs.
	WHO-Research and Training Centre in Immunology.	WHO	\$2000.00	The grant will be available when WHO formally nominates NII as the WHO-RTC Centre in Immunology for South East Asia. Government of India, DST and Ministry of Health & Family Welfare have concurred to proposal to nominate NII as the WHO Centre.

47

Scientific Advisory Committee of the
National Institute of Immunology

- | | |
|--|------------------|
| 1. Prof. V. Ramalingaswami,
Director-General, ICMR. | Chairman |
| 2. Dr. S. Ramachandran,
Adviser (Bio-technology), DST | Member |
| 3. Dr. P.M. Bhargava,
Director, CCFB, Hyderabad. | " |
| 4. Dr. O. Siddiqui,
TIFR, Bombay. | " |
| 5. Dr. S. Acharya,
Director, I.C.A.R., New Delhi | " |
| 6. Prof. G.P. Talwar,
Director, N.I.I. | Member-Secretary |