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PROGRAM FOR APPLIED RESEARCH
ON FERTILITY REGULATION

S E M I - A N N U A L R E P O R T

January 1, 1982 - June 30, 1982

Submitted to: Research Division
 Office of Population
 Development Support Bureau
 Agency for International Development
 Washington, D.C. 20523

Submitted by: Program for Applied Research on
 Fertility Regulation
 Northwestern University Medical School
 Suite 1525
 875 N. Michigan Avenue
 Chicago, Illinois 60611

In compliance with Contract AID/csd-3608,
Contract AID/DSPE-C-0035 and
Cooperative Agreement DPE-0546-A-00-1003-00

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<u>Research Frontiers in Fertility Regulation</u>	
Volume 2, Number 1, June, 1982	

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REPORT SUMMARY

Project Title and Contract Number:

Program for Applied Research on Fertility Regulation
AID/csd-3608
AID/DSPE-C-0035
DPE-0546-A-00-1003-00

Principal Investigator:

John J. Sciarra, M.D., Ph.D.
Professor and Chairman
Department of Obstetrics and Gynecology
Prentice Women's Hospital and Maternity Center
333 East Superior Street
Chicago, Illinois 60611

Contractor:

Northwestern University
c/o Sponsored Projects Administration
619 Clark Street
Evanston, Illinois 60201

Contract Period:

July 1, 1975 - June 30, 1979 -- AID/csd-3608
July 1, 1979 - June 30, 1981 -- AID/DSPE-C-0035
July 1, 1981 - June 30, 1986 -- DPE-0546-A-00-1003-00

Reporting Period:

January 1, 1982 - June 30, 1982

Total Expenditures Through December 31, 1981:

AID/csd-3608	\$4,331,521.82
AID/DSPE-C-0035	2,866,891.28
DPE-0546-A-00-1003-00	<u>201,345.38</u>
TOTAL:	\$7,399,758.48

Total Expenditures January 1, 1982 Through June 30, 1982:

AID/csd-3608	\$ - 0 -
AID/DSPE-C-0035	399,626.04
DPE-0546-A-00-1003-00	<u>448,582.84</u>
TOTAL:	\$ 848,208.88

Commitments Through June 30, 1982:

AID/DSPE-C-0035	\$ 134,545.74
DPE-0546-A-00-1003-00	<u>514,723.06</u>
TOTAL:	\$ 649,268.80

COOPERATIVE AGREEMENT OBJECTIVES

The recipient shall perform a research and development program directed toward actively pursuing a number of promising leads of goal-directed research to develop new or improved means of fertility control suitable for use in Less Developed Countries (LDCs). This research will include innovative projects to develop and clinically evaluate improved means of male and female sterilization, studies of male pharmacologic methods, post-coital/post-ovulatory methods of fertility control, contragestational methods, self-administered methods, long-acting methods and intrauterine delivery systems.

An administrative/technical/scientific unit backed up by a Scientific Advisory Committee (SAC) composed of experts actively engaged in reproductive research will continue to actively solicit, screen, develop, recommend for funding, review, and monitor sharply focused fertility research projects from the U.S. and overseas institutions.

General Objectives

1. To develop new or improved means of fertility regulation suitable for use in less developed countries through actively pursuing and funding of research subagreements in institutions in the United States, other developed countries and less developed countries, or through collaborative projects among such institutions.

2. To strengthen, encourage and support applied contraceptive research by means of, but not limited to, such activities as subagreement research and workshops on topics of scientific and programmatic importance.

PROGRAM ACCOMPLISHMENTS

LDC Involvement

PARFR, with the Universidad de Chile, supported a post-graduate Course, "Clinical Aspects of Human Reproduction," which was held April 15-17, 1982 in Santiago, Chile. The course was attended by 318 participants, representing 9 Latin American countries. Some of these participants attended with the support of the local AID Mission and IDRC.

Two PARFR staff members participated in the symposium: Dr. Alfredo Goldsmith, in addition to serving as co-director, authored and presented: "Vaginal Contraceptives," and Dr. Gerald Zatuchni authored and presented: "Contraception in the Year 2000." Dr. Zatuchni also presented: "Complications of Female Sterilization," by Dr. John J. Sciarra.

Prior to the course, proceedings were edited, published and typed in Spanish by PARFR staff. The proceedings were subsequently distributed to course participants and selected researchers and libraries in Latin America.

In addition to Drs. Goldsmith and Zatuchni, PARFR sponsored the following participants: Ricardo H. Asch, M.D., Leonard E. Laufe, M.D., Kamran S. Moghissi, M.D., Carl J. Pauerstein, M.D., Ralph M. Richart, M.D., Joe Leigh Simpson, M.D., Aquiles J. Sobrero, M.D., Emil Steinberger, M.D. and Rafael Valle, M.D.

Dr. Alfredo Goldsmith was also active as a member of the Special F.I.G.O. Committee on Medical Aspects of Human Reproduction, and as a lecturer and consultant editor of the Community and Family Studies Center (summer workshop for LDC students) sponsored by Dr. Bogue at the University of Chicago.

During this report period, January 1, 1982 - June 30, 1982, the following subcontracts in LDCs terminated:

1. *PARFR-200P -- "Phase I Clinical Trial of Fallopian Tube Closure Using Methylcyanoacrylate (MCA) Delivered Through the Single Application Fertility Regulation (FEMCEPT) Device"
Ruben A. Apelo, M.D., JFMH Comprehensive Family Planning Center, Manila, Philippines
2. *PARFR-225B -- "Clinical Trials of the Norethisterone Microcapsule Injectable Contraceptive System"
Elsimar M. Coutinho, M.D., Maternidade Climerio de Oliveira, Salvador, Bahia, Brazil
3. *PARFR-225Ma -- "Clinical Trials of the Norethisterone Microcapsule Contraceptive System"
Roberto Rivera, M.D., Instituto de Investigacion Cientifica, Durango, Mexico
4. PARFR-226B -- "Clinical Trial of Fallopian Tube Closure Using MCA"
Elsimar M. Coutinho, M.D., Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil

LDC Involvement (cont'd)

5. PARFR-227B -- "Prostaglandin Levels in the Human Follicular Fluid in Relation to the Moment of Ovulation"
Hugo Maia, M.D., Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil
6. *PARFR-229B -- "Studies on Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implants"
Elsimar M. Coutinho, M.D., Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil
7. *PARFR-229M -- "A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant"
Roberto Rivera, M.D., Instituto de Investigacion Cientifica, Durango, Mexico
8. PARFR-238C -- "Radio-Opaque MCA - Cineflourography Study"
Rene Guzman-Serani, M.D., Universidad Austral de Chile, Valdivia, Chile

* Final financial and technical reports had not been received as of 6/30/82.

The following subagreements (in LDCs) were executed during the period January 1, 1982 - June 30, 1982:

1. PARFR-310C -- "MCA/FEMCEPT Video Study"
Enrique Guiloff, M.D., Santiago, Chile
2. PARFR-311C -- "Uterine Measurement - Clinical Comparison Study (Wing Sound II)"
Rene Guzman-Serani, M.D., Universidad Austral de Chile, Valdivia, Chile
3. PARFR-314E -- "Uterine Measurement - Clinical Comparison Study (Wing Sound II)"
Mokhtar Topozada, M.D., Shatby University Hospital, The University of Alexandria, Alexandria, Egypt
4. PARFR-316C -- "MCA/FEMCEPT Study"
Rene Guzman-Serani, M.D., Universidad Austral de Chile, Valdivia, Chile
5. PARFR-318B -- "MCA/FEMCEPT Study"
Elsimar M. Coutinho, M.D., Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil

PROGRAM ACCOMPLISHMENTSScientific Summary

1. PARFR's staff and Scientific Advisory Committee (SAC) conducted reviews of extension, formal, pilot study and informal research proposals received during this reporting period. Please refer to the SAC section (Program Accomplishments) and SAC Minutes (Appendix) for specific determinations.
2. The staff, SAC and consultants monitored research progress by review of technical reports and site visits. The following projects were visited during this reporting period:
 - a. 2/8-16/82 - Diane Krier-Morrow, Salvador, Bahia, Brasil and Caracas, Venezuela
(PARFR-225B, PARFR-226B, PARFR-227B, PARFR-229B and 305V)
 - b. 4/27-29/82 - Diane Krier-Morrow, Durango, Mexico
(PARFR-225Ma and 229M)
 - c. 5/24/82 - Drs. Goldsmith and Moghissi, New York, New York
(PARFR-229 and 312)
3. Drs. Goldsmith and Zatuchni attended a meeting of the American Fertility Society on March 21-24, 1982 in Las Vegas, Nevada on PARFR's behalf.
4. Dr. Gerald Zatuchni attended a meeting on Contraceptive Development, June 8-9, 1982, in New York, New York on PARFR's behalf.
5. Dr. Alfredo Goldsmith served as co-director of the post-graduate course "Clinical Aspects of Human Reproduction," April 15-17, 1982, in Santiago, Chile. Dr. Alfredo Goldsmith prepared a presentation "Vaginal Contraceptives," Dr. John Sciarra prepared a presentation entitled "Complications of Female Sterilization" and Dr. Gerald Zatuchni prepared a presentation entitled: "Contraception in the Year 2000," for the Santiago symposium.
6. PARFR held its 12th International Workshop "Non-Surgical Methods for Female Tubal Occlusion," June 22-24, 1982 at the Ambassador East Hotel in Chicago. Sixty-five persons attended, representing 14 countries.
7. Volume 2, Number 1 of PARFR's research technical information report was produced and distributed. The issue, "Current Status of Plant Products Reported to Inhibit Sperm" was co-authored by Norman R. Farnsworth, Ph.D. and Donald P. Waller, Ph.D. (please refer to the Appendix for a copy of the publication).
8. Publication and distribution of the book "LHRH Peptides as Female and Male Contraceptives" developed from the proceedings of PARFR's 11th International Workshop was completed during this reporting period.
9. On June 23, 1982, PARFR relocated its offices to Suite 1525, 875 N. Michigan Avenue, Chicago, Illinois 60611 and was able to resume full activity on June 30, 1982.

PROGRAM ACCOMPLISHMENTS

Administrative Summary

In addition to the routine management of the program, the efforts of the PARFR Administrative Staff were chiefly directed toward:

1. Monitoring Cooperative Agreement, DPE-0546-A-00-1003-00 which became effective 7/1/81.
2. Monitoring prior research commitments under Contract AID/DSPE-C-0035, which terminated 6/30/82.
3. Coordinating and mailing agendas for two meetings of the Scientific Advisory Committee, held on March 13, 1982 and June 25, 1982. The March 13th agenda included 3 extension proposals; 1 pilot study proposal, 3 formal proposals and 1 informal proposal, as well as 24 technical reports. The June 25th agenda consisted of 6 extension proposals, 6 formal proposals, 1 informal proposal and 14 technical reports.
4. Negotiating and executing eleven new subagreements:
(307, 308, 309, 310C, 311C, 312, 313E, 314E, 315, 316C and 318B),
14 no-cost extension amendments (200P, 207, 212(85N), 225B, 225Ma, 226C, 229B, 229M, 232, 233, 235UAB, 236IIT, 304, 312) and
3 amendments adding an article to the subagreement (302, 303, 304).
5. Mailing 6,000 copies of Vol. 2, Number 1 of the Research Frontiers in Fertility Regulation series.
6. Distributing 1,500 copies of the book "LHRH Peptides as Female and Male Contraceptives".
7. Planning, coordinating and executing the 12th International Workshop "Non-Surgical Methods for Female Tubal Occlusion" held June 22-24, at the Ambassador East Hotel in Chicago, Illinois.
8. Relocating PARFR offices to 875 N. Michigan Avenue in Chicago. Preparation for the move, which took place on June 28, 1982, included negotiation of a 4-year lease between Northwestern University and Sudler and Company, leasing agent, and sending notification of the change of address to approximately 10,000 individuals and institutions.
7. The program staff during this reporting period was:

John J. Sciarra, M.D., Ph.D.	Program Director
Diane Krier-Morrow, M.B.A.	Director of Administration
Gerald I. Zatuchni, M.D., M.Sc.	Director of Technical Assistance
Alfredo Goldsmith, M.D., M.P.H.	Head, Research Project Development
Ann Conner Nickle (term. 2/28/82)	Project Controller
Susan Dewar (start 3/29/82)	Project Controller
Ruvenia Thomas	Secretary II
Asenath Williamson	Secretary I
Rebecca Zaccard	Secretary I

1/1/82 - 6/30/82

AID/DSPE-C-0035

Subcontract Negotiations

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
200P	"MCA/FEMCEPT Study" Ruben A. Apelo, M.D. JFMH Comprehensive Family Planning Center Manila, Philippines	No-Cost Extension Revised Budget (Amendment #2)	10/1/79- 6/30/82	
207	"Hysteroscopic Sterilization by Using Uterotubal Blocking Devices" Abdol H. Hosseinian, M.D. Hektoen Institute for Medical Research Chicago, Illinois	No-Cost Extension (Amendment #3)	11/1/79- 6/30/82	
212(85N)	"Development of Collagen Sponge Containing Spermicide and Post-Coital Testing of Collagen Sponge Diaphragm" Milos Chvapil, M.D., Ph.D. University of Arizona Health Sciences Center Tucson, Arizona	No-Cost Extension (Amendment #4)	3/1/80- 6/30/82	
225B	"Clinical Trials of the Norethisterone Microcapsule Injectable Contraceptive System" Elsimar M. Coutinho, M.D. Maternidade Climerio de Oliveira Salvador, Bahia, Brasil	No-Cost Extension (Amendment #4)	7/1/81- 6/30/82	

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
225Ma	"Clinical Trials of the Norethisterone Microcapsule Injectable Contraceptive System" Roberto Rivera, M.D. Instituto de Investigacion Cientifica Durango, Mexico	No-Cost Extension (Amendment #1)	7/1/81- 6/30/82	
226C	"Clinical Trials of Fallopian Tubal Closure Using MCA" Rene Guzman-Serani, M.D. Universidad Austral de Chile Valdivia, Chile	No-Cost Extension Revised Budget (Amendment #1)	4/1/81- 6/30/82	
229B	"Studies on Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant" Elsimar M. Coutinho, M.D. Maternidade Climerio de Oliveira Salvador, Bahia, Brasil	No-Cost Extension (Amendment #1)	3/1/81- 6/30/82	
229M	"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant" Roberto Rivera, M.D. Instituto de Investigacion Cientifica, Universidad Juarez del Estado Durango, Mexico	No-Cost Extension (Amendment #1)	3/1/81- 6/30/82	
232	"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase-C4" Erwin Goldberg, M.D. Northwestern University Evanston, Illinois	No-Cost Extension (Amendment #1)	3/1/81- 3/15/82	

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
233	"Potentially Antifertility Activity of LH/HCG Peptide Fragments" Joseph W. Goldzieher, M.D. Southwest Foundation for Research and Education San Antonio, Texas	No-Cost Extension (Amendment #3)	4/15/81- 5/14/82	
235UAB	"A Fibrous Polymer for the Delivery of Contraceptive Steroid to the Female Reproductive Tract - Continuation of PARFR-206UAB" Lee R. Beck, Ph.D. University of Alabama in Birmingham Birmingham, Alabama	No-Cost Extension (Amendment #1)	4/1/81- 6/30/82	
236IIT	"Retinoids and Male Contraception" Rajendra G. Mehta, Ph.D. IIT Research Institute Chicago, Illinois	No-Cost Extension (Amendment #1)	6/1/81- 6/30/82	

1/1/82 - 6/30/82

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Subagreement Negotiations

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
302	"Studies on the Anti-Fertility Effects of a Potent LHRH Inhibitory Analog (Antagonist) in the Cynomolgus Monkey" Ricardo H. Asch, M.D. The University of Texas Health Science Center at San Antonio San Antonio, Texas	Addition of Article: "Care of Laboratory Animals" (Amendment #1)		
303	"Investigation of FCE 20340 as an Anti-Fertility Agent When Administered Parenterally or Orally" Leonard J. Lerner, Ph.D. Jefferson Medical College of Thomas Jefferson Univ. Philadelphia, Pennsylvania	Addition of Article: "Care of Laboratory Animals" (Amendment #1)		
304	"Evaluation of Anti-Fertility Effects of a Potent LHRH Antagonist in the Guinea Pig as a Preclinical Model" Walter G. Weist, Ph.D. Washington University Medical School St. Louis, Missouri	Addition of Article: "Care of Laboratory Animals" (Amendment #1)		
		No-Cost Extension (Amendment #2)	9/1/81- 7/31/82	
307	"Development of Sperm Enzyme Inhibitors as Vaginal Contraceptives - Continuation of PARFR-204" Lourens J.D. Zaneveld, D.V.M., Ph.D. University of Illinois at the Medical Center Chicago, Illinois	New Subagreement	1/1/82- 12/31/82	\$ 64,353

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
308	"Transcutaneous Ablation of Cauda Epididymis in Non-Human Primates" Ronald W. Lewis, M.D. Tulane University Covington, Louisiana	New Subagreement	1/1/82- 12/31/82	\$ 39,595
309	"Ovulation Inhibition by Anordrin" Raksha Mehta, Ph.D. Northwestern University Medical School Chicago, Illinois	New Subagreement	1/1/82- 6/30/82	31,903
310C	"MCA/FEMCLPT Video Study" Enrique Guilloff, M.D. Santiago, Chile	New Subagreement	1/1/82- 6/30/82	8,000
311C	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)" Rene Guzman-Serani, M.D. Universidad Austral de Chile Valdivia, Chile	New Subagreement	3/1/82- 8/31/83	7,500
312	"A Clinical Evaluation of the Subdermal Contraceptive Norethindrone Pellet - Continuation of PARFR-229" Brij B. Saxena, Ph.D., D.Sc. The Cornell University Medical College New York, New York	New Subagreement No-Cost Extension	1/1/82- 5/31/82 1/1/82- 7/31/82	33,356
313E	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)" Robert Snowden, Ph.D. Institute of Population Studies, University of Exeter Devon, England	New Subagreement	2/1/82- 7/31/83	21,600

PROJECT #	TITLE/INVESTIGATORS/INSTITUTION	ACTION	PERIOD	FUNDING
314E	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)" Mokhtar Topozada, M.D. Shatby Hospital, The University of Alexandria Alexandria, Egypt	New Subagreement	2/1/82- 7/31/83	\$ 5,400
315	"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase-C ₄ - Extension of PARFR-232" Erwin Goldberg, Ph.D. Northwestern University Evanston, Illinois	New Subagreement	3/1/82- 2/28/83	53,736
316C	"MCA/FEMCEPT Study" Rene Guzman-Serani, M.D. Universidad Austral de Chile Valdivia, Chile	New Subagreement	4/1/82- 3/31/84	24,000
318B	"MCA/FEMCEPT Study" Elsimar M. Coutinho, M.D. Maternidade Climerio de Oliveira Salvador, Bahia, Brasil	New Subagreement	5/1/82- 4/30/83	14,982

PERSONNEL

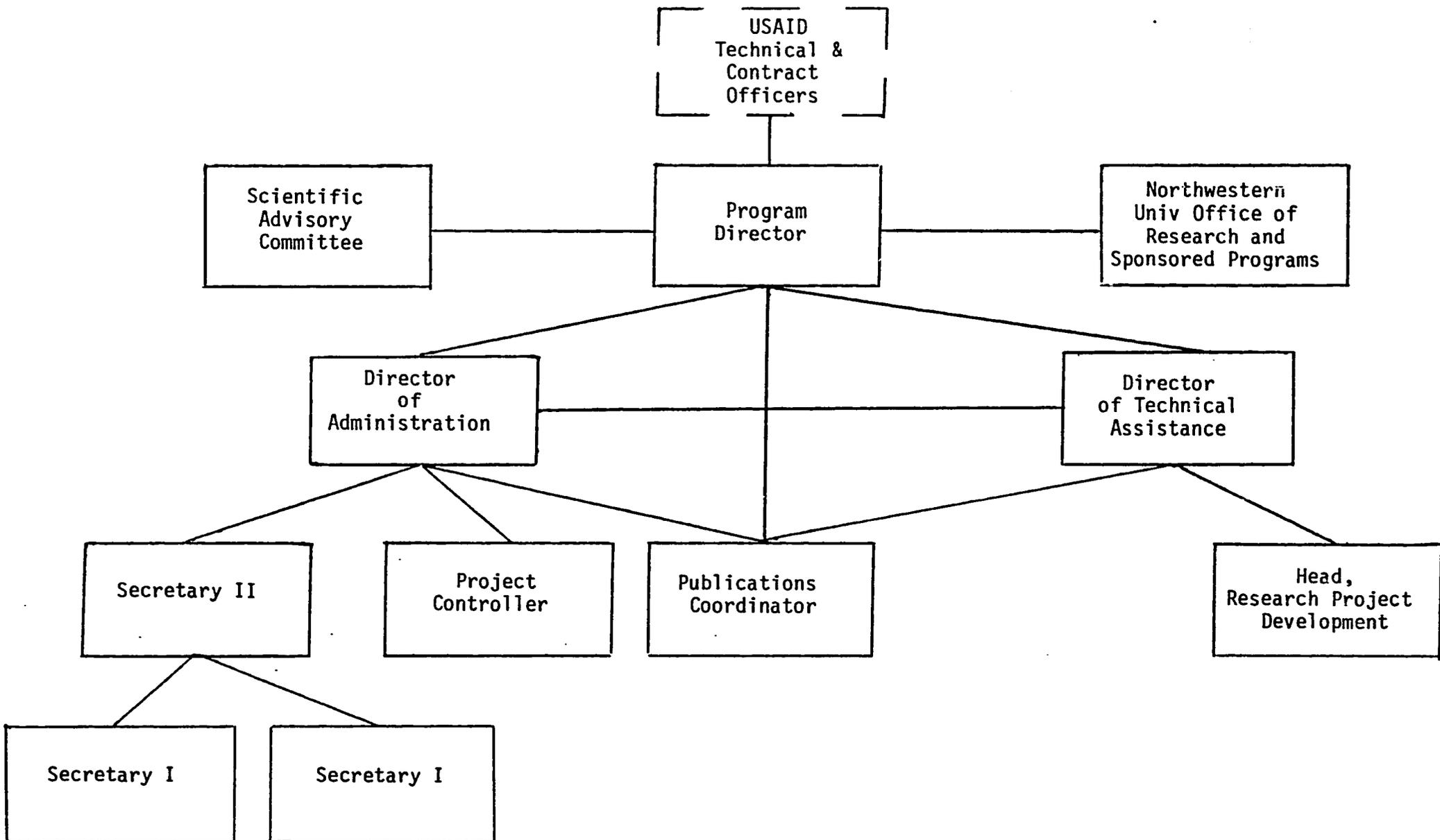
Effort and salary expenditures of PARFR personnel for this reporting period are listed below:

<u>Staff and Title</u>	<u>Effort in Man-months</u>	<u>Salary</u>
John J. Sciarra, M.D., Ph.D. Director and Principal Investigator	.6	\$ 2,875.02
Gerald I. Zatuchni, M.D., M.Sc. Director of Technical Assistance	4.8	\$20,044.98
Alfredo Goldsmith, M.D., M.P.H. Head, Research Project Development	5.4	25,875.00
Diane Krier-Morrow, M.B.A. Director of Administration	6.0	13,750.02
Ann Conner Nickle (Term. 2/28/82) Project Controller	2.0	3,554.40
Susan Dewar (Start 3/29/82) Project Controller	3.0	4,173.90
Kelley Osborn Publications Coordinator	0.6	2,235.00
Ruvenia Thomas Secretary II	6.0	8,571.00
Asenath Williamson (Start 8/17/81) Secretary I	6.0	6,275.36
Rebecca Zaccard (Start 8/17/81) Secretary I	4.5	6,324.00
<u>Fringe Benefits</u>		\$14,480.99
<u>Indirect Costs</u>		53,741.89

Administrative Organization

The program staff is structured according to the chart on the following page.

PARFR Organization Chart



SCIENTIFIC ADVISORY COMMITTEE

The membership of the Scientific Advisory Committee during this reporting period consisted of the following individuals:

John J. Sciarra, M.D., Ph.D., Chairman	Northwestern University
Nancy J. Alexander, Ph.D.	Oregon Regional Primate Research Center
David A. Blake, Ph.D.	The Johns Hopkins University School of Medicine
Robert T. Chatterton, Ph.D.	Northwestern University
Elizabeth B. Connell, M.D.	Emory University School of Medicine
Joseph E. Davis, M.D.	New York Medical College
Miriam H. Labbok, M.D., M.P.H.	The Johns Hopkins School of Hygiene and Public Health
Kamran S. Moqhissi, M.D.	Wayne State University
Dean L. Moyer, M.D.	University of Southern California School of Medicine
Susan C.M. Scrimshaw, Ph.D. (terminated 3/82)	University of California at Los Angeles
Rochelle N. Shain, Ph.D. (started 6/82)	The University of Texas Health Science Center at San Antonio
Aquiles J. Sobrero, M.D.	Northwestern University

The Scientific Advisory Committee (SAC) met twice during this reporting period: March 13, 1982 and June 25, 1982; both meetings were held in Chicago, Illinois. Minutes of these meetings are included in the Appendix.

At the March 13, 1982 SAC Meeting, the Committee reviewed 24 technical reports. Twelve of these were final reports.

Three extension proposals were reviewed by the Committee: PARFR-205(95N) was approved with a reworked proposal; PARFR-232 was approved with a reduced budget; PARFR-229 was not approved pending receipt of a full, comprehensive technical report on the cases enrolled in the study.

Two informal proposals were reviewed. The Committee recommended pilot funding to James W. Simpkins, M.D., whose proposal was entitled "Fertility Regulation Through Sustained Exposure to Narcotic Antagonists."

Three formal proposals were reviewed. The Committee voted to approve a pilot study with recommended revisions on the following proposal:

"Guaiacol Peroxidase Levels in Cervical Mucus, Saliva and Vaginal Secretions: Possible Predictors of Ovulation"
John C.M. Tsibris, Ph.D., University of Illinois College of Medicine

At the June 25, 1982 meeting, the Committee reviewed 14 technical reports, of which 4 were final reports.

The Committee reviewed six extension proposals. PARFR-309 was approved with a recommendation to reduce the budget. A modified proposal for PARFR-235SRI was approved. PARFR-312 was carefully considered and evaluated, but not approved until current studies and reports are completed. PARFR-212(85N)

Scientific Advisory Committee (cont'd)

was not approved because the barrier method studied was not viewed as an improvement over other developments. PARFR-304 was not approved due to the inappropriateness of the guinea pig model in this study. PARFR-236IIT was not approved as presented.

Six formal proposals were reviewed. The following three proposals were approved with modifications: Dr Luukanien's "Studies on the Effectiveness of a Progestin-Releasing Intracervical Device;" Dr. Louren J.D. Zaneveld's "Efficacy of Quinacrine Pellets in the Primate;" and Dr. Richard J. Dunn's "Development of a Fibrous IUD Delivery System for Estradiol/Progesterone."

After evaluating Dr. Horacio B. Croxatto's informal proposal "Progesterone Microcapsules," the Committee recommended submission of a formal proposal.

CONSULTANTS

The following is a list of Program Consultants, indicating their areas of expertise, contributions to the program, and payment therefore. Included in this list of consultants are members of the Scientific Advisory Committee.

<u>Consultant</u>	<u>Purpose</u>	<u>Effort</u>	<u>Fee</u>
Nancy J. Alexander, Ph.D. Reproductive Physiology	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	\$ 385.48 385.48
David A. Blake, Ph.D. Obstetrics and Gynecology Pharmacology	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Robert T. Chatterton, Ph.D. Steroid Biochemistry	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Elizabeth B. Connell, M.D. Obstetrics and Gynecology	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Joseph E. Davis, M.D. Urology	SAC 6/24-25/82	2 days	385.48
David A. Edelman, Ph.D. Biostatistician	Project Consultation 3/16/82	1 day	192.74
Norman R. Farnsworth, Ph.D. Pharmacognosy	RFFR Series Vol. 2, No. 1 4/16-18/82	3 days	600.00
Miriam H. Labbok, M.D., M.P.H. Epidemiology	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Kamran S. Moghissi, M.D. Obstetrics and Gynecology Reproductive Endocrinology	SAC 3/12-13/82 Site Visit -- 6/9/82 PARFR-229 & 312 Proposal Review 6/4/82	2 days 1 day 1 day	385.48 150.00 50.00
Dean L. Moyer, M.D. Experimental Pathology	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Antonio Scommegna, M.D. Obstetrics and Gynecology IUDs	Proposal Review 5/22/82	1 day	50.00
Susan C.M. Scrimshaw, Ph.D. Medical Anthropology	SAC 3/12-13/82	2 days	385.48

Consultants (cont'd).

Rochelle N. Shain, Ph.D. Medical Anthropology	SAC 6/24-25/82	2 days	\$ 385.48
Aquiles J. Sobrero, M.D. Infertility	SAC 3/12-13/82 SAC 6/24-25/82	2 days 2 days	385.48 385.48
Kenneth A. Tung, M.D. Pathology	Proposal Review 3/8/82	1 day	50.00
Donald P. Waller, Ph.D. Pharmacology	RFFR Series Vol. 2, No. 1 4/16-18/82	3 days	450.00
		TOTAL	<hr/> \$ 8,481.38

RESEARCH

PARFR SUBCONTRACT/SUBAGREEMENT SUMMARIES

This section includes summaries of PARFR subcontracts and subagreements active during the period January 1, 1982 to June 30, 1982. Summaries are categorized according to the following AID Contraceptive Research Areas:

- I. Female Sterilization
 - C. Transcervical
 - B. Reversible
- II. Male Sterilization
 - B. Other
- III. Intrauterine Contraception
 - D. Other
- IV. Systemic Contraception
 - B. Injectables and Implants
 - C. Other
 - 1. Male Pharmacological Methods
- V. Barrier Contraception
 - B. Female
- VI. Pregnancy Tests
- VII. Miscellaneous

RESEARCH

I. FEMALE STERILIZATION

C. TRANSCERVICAL

Title: "Phase I Clinical Trials of Fallopian Tube Closure Using Methylcyanoacrylate (MCA) Tissue Delivered Through the Single Application Fertility Regulation (FEMCEPT) Device"

Objective: To determine the safety and efficacy of the FEMCEPT device for the delivery of MCA to the fallopian tubes of human volunteers.

PARFR-200K(86K) Sung-bong Hong, M.D.
Korea University College of Medicine
Seoul, Korea

Period: 5/1/80-8/31/82 Budget: \$2,598
 5/1/79-4/30/80 Expended: 9,140.41 (86K)

PARFR-200P Ruben A. Apelo, M.D.
Jose Fabella Memorial Hospital
Manila, Philippines

Period: 10/1/79-6/30/82 Budget: \$14,385

Title: "MCA/FEMCEPT Study"

Objective: To determine if the tubal occlusion rate obtained by a single application of MCA delivered through the FEMCEPT device can be improved either by uterine lavage prior to application, and/or using two consecutive monthly applications.

PARFR-316C/226C Rene Guzman-Serani, M.D.
Universidad Austral de Chile
Valdivia, Chile

Period: 4/1/82-3/31/84 Budget: \$24,000
 4/1/81-6/30/82 Expended: 24,145 (226C)

PARFR-318B/226B Elsimar Metzker Coutinho, M.D.
Maternidade Climerio de Oliveira
Salvador, Bahia, Brasil

Period: 5/1/82-4/30/83 Budget: \$14,982
 9/15/80-6/30/82 Expended: 41,304.55 (226B)

Title: "Data Collection and Analysis of MCA/FEMCEPT Clinical Trials"

Objective: To provide technical service in the form of monitoring data processing and statistical analysis of the PARFR-supported clinical trials with the MCA/FEMCEPT system of non-surgical female sterilization.

PARFR-240 Ralph M. Richart, M.D. and Robert S. Neuwirth, M.D.
Presbyterian Hospital Obstetrical and Gynecological Service
New York, New York

Period: 7/1/80-6/30/82 Budget: \$24,440

Title: "Radio-Opaque MCA-Repeated X-ray HSG Study"

Objective: To test whether the behavior of MCA is different with the addition of a radio-opaque polymerization inhibitor and to better understand the dynamics of the FEMCEPT application process.

PARFR-238C Rene Guzman-Serani, M.D.
Universidad Austral de Chile
Valdivia, Chile

Period: 6/15/81-3/14/82 Expended: \$6,975

Title: "MCA/FEMCEPT Video Study"

Objective: Using flouroscopy at the time of MCA/FEMCEPT treatment, to test whether the behavior of MCA is different with the addition of a radio-opaque polymerization inhibitor and to better understand the dynamics of the FEMCEPT application process.

PARFR-310C Enrique Guiloff, M.D.
Santiago, Chile

Period: 1/1/82-6/30/83 Budget: \$8,000

Title: "Radio-Opaque Methylcyanoacrylate (MCA) Delivered Through the Single Application (FEMCEPT) Device"

Objective: To determine the tubal occlusion rate obtained by a single application of MCA delivered through the FEMCEPT device.

PARFR-305V

Itic Zigelboim, M.D. and Wiktor Szczedrin, M.D.
 Maternidade "Concepcion Palacios"
 Caracas, Venezuela

Period: 9/10/81-9/9/82 Budget: \$17,225

Direct Payment
D-21

Badri Saxena, Ph.D.
 ICMR
 New Delhi, India

Expended: \$1,301.80

MCA/FEMCEPT
RESULTS:

Two types of MCA and two modalities of application were tested in human clinical trials.

As of June 30, 1982, results indicate that single application of MCA shows a 75% bilateral occlusion rate, which is increased to 80% when radio-opaque MCA is used. Uterine lavage prior to application does not increase the rate of bilateral tubal occlusion; however, two applications separated by one month provide a 90% bilateral tubal occlusion rate.

Data on MCA/FEMCEPT research gathered during the period January 1, 1982 - June 30, 1982 was analyzed by the Obstetrical and Gynecological Service of the Presbyterian Hospital in New York. After June 30, 1982, data management responsibilities will be transferred to BioNexus, Inc., the company that manufactures MCA and FEMCEPT devices.

I. FEMALE STERILIZATION

D. REVERSIBLE

Title: "An Evaluation of the Efficacy of Fimbrial Enclosure With Silastic Devices as a Reversible Female Sterilization Technique"

Objective: To determine the reversibility of sterilization by fimbrial enclosure with specially designed silastic fimbrial hoods in adult female Rhesus monkeys.

PARFR-217(111N)

Carlton A. Eddy, Ph.D.
 The University of Texas Health Sciences Center at San Antonio
 San Antonio, Texas

Period: 7/1/80-5/31-82 Expended: \$55,467.11
 6/1/79-6/30/80 Expended: 55,258 (111N)

PARFR-217(111N)
RESULTS:

Silastic devices were fitted bilaterally in 20 primates. The animals were followed via laparoscopic examination and breeding experiments. One animal became pregnant one month after the enclosure technique, due to spontaneous detachment of the device on one tube. An additional animal has died of causes not related to the surgery. Unfortunately, detachment of the devices occurred in a significant number of the animals, within approximately 2 months of the surgical procedure, despite the use of 6 to 8 interrupted 9-0 nylon suture. In the animals in which the device remained for a significant period of time, the silastic material has shown remarkable inertness and freedom from tissue reactivity. Adhesions, when present, have been minor. Histo-logic examination of the enclosed fimbria revealed no tubal damage, even under electron microscopy.

The principal investigator, in collaboration with Leonard E. Laufe, M.D. and K.L.I., is in the process of applying for an Investigational Device Exemption to permit testing of the silastic fimbrial hood in India and the U.S.

Title: "Hysteroscopic Sterilization by Using Uterotubal Blocking Devices"

Objective: To determine, in selected volunteer women, the contraceptive efficacy of the Uterotubal Junction (UTJ) plug.

PARFR-207 Abdol H. Hosseinian, M.D.
 Cook County Hospital
 Chicago, Illinois

Period: 11/1/79-6/30/82 Budget: \$24,348

RESULTS: Due to the inavailability of the steerable hysteroscope, no activities have been reported on this project.

II. MALE STERILIZATION

B. OTHER

Title: "Transcutaneous Ablation of Cauda Epididymis in Non-Human Primates"

Objective: To determine if ablation of the epididymal tract is possible by the transcutaneous method; if resultant azoospermia occurs and to assess the extent and type of injury to the epididymis, testis and surrounding tissues.

PARFR-308 Ronald W. Lewis, M.D.
Delta Regional Primate Research Center
Covington, Louisiana

Period: 1/1/82-12/31/82 Budget: \$39,595

RESULTS: During this period, epididymal ablation by percutaneous injection or an open surgical procedure was performed in three groups of Macaca fascicularis monkeys using three agents. Group I had a 0.5 cc of 4% formaldehyde in glycerol injected into the epididymis with the following results: two animals were azoospermic at one week, two animals were azoospermic at 3 1/2 weeks, and one animal injected percutaneously had an elevated sperm count at 3 1/2 weeks after initially decreasing at 10 days. The last animal is continuing to be ejaculated at weekly intervals. Group II had 0.5 cc of MCA injected into the epididymis with the following results: two were azoospermic at 10 days and three were azoospermic at 2 1/2 to 3 weeks. One animal injected at open surgery died the day of surgery; autopsy did not reveal aspiration or other cause of death. Group III had 100 mgm of Quinacrine hydrochloride in 2.0 cc of sterile saline injected into the epididymis with the following result: 3 animals were azoospermic 2 1/2-3 weeks after injection and one animal recently ablated had sperm present at one week. Three Quinacrine injected animals died, two, the original day of injection; and one, one week after surgery. Autopsy did not reveal the cause of death. A serum toxicology screen was performed on the second animal that died and Ketamine level was 8 ucg/ml. Two of these animals had been treated for malaria during their quarantine period. All animals had excellent sperm counts before ablation.

In all animals local reactions to injections have resulted in only one small abscess that cleared spontaneously and for the most part injection resulted in a firm cauda epididymis with fixation to the scrotal skin.

III. INTRAUTERINE CONTRACEPTION

D. OTHER

Title: "Uterine Measurement - Clinical Comparison Study (Wing Sound II)"

Objective: To evaluate the performance of IUDs in terms of two-dimensional uterine size: namely, endometrial cavity length and width. The dimensions of the cavity will be determined using the Wing Sound II.

PARFR-311C Rene Guzman-Serani, M.D.
Universidad Austral de Chile
Valdivia, Chile

Period: 3/1/82-8/31/83 Budget: \$7,500

PARFR-313E Robert Snowden, Ph.D.
University of Exeter
Devon, England

Period: 2/1/82-7/31/83 Budget: \$21,600

PARFR-314E Mokhtar Topozada, M.D.
The University of Alexandria
Alexandria, Egypt

Period: 2/1/82-7/31/83 Budget: \$5,400

Title: "Design and Manufacture of 1,500-2,000 Wing Sound II Devices"

Objective: To design and coordinate the manufacture of 1,500 to 2,000 Wing Sound II devices.

PARFR-230 H.F.D. Design
Crystal Lake, Illinois

Period: 11/1/81-3/15/82 Expended: \$33,000

Wing Sound II
RESULTS:

Wing Sound II's were distributed to all centers. Studies were initiated in all centers during this reporting period. Data is being monitored by the IFRP.

IV. SYSTEMIC CONTRACEPTION

B. INJECTABLES AND IMPLANTS

Title: "Clinical Trials of the Norethisterone Microcapsule Injectable Contraceptive System"

Objective: To test a long-acting injectable contraception system which provides continuous release of norethisterone for a precise period of six months following a single intramuscular injection. The system consists of microcapsules made of the biodegradable polymer d,l-polylactic acid, in which micronized crystals of NET are homogeneously dispersed.

PARFR-225B Elsimar M. Coutinho, M.D.
Maternidade Climerio de Oliveira
Salvador, Bahia, Brasil

Period: 4/1/81-6/30/82 Expended: \$28,209.38

PARFR-225Ma Roberta Rivera, M.D.
Instituto de Investigacion Cientifica
Durango, Mexico

Period: 4/1/81-6/30/82 Expended: \$40,298.50

RESULTS: The NET system has been shown to be effective in the suppression of ovulation over a 180-day period, to have a virtually constant rate of release of NET into the system, and to have no significant side effects. In a preliminary human drug release study, microcapsule doses containing between 7.25 and 94.5 mg of NET were tested. On the basis of this study it was determined that larger doses are necessary to inhibit ovulation for the full six months. Patients in the Mexico study were treated with 800 mg of microcapsules containing 200 mg of NET and patients in the Brasil study were treated with 600 mg of microcapsules containing 150 mg of NET.

Title: "Clinical Trials of the Norethisterone Injectable Contraceptive System"

Objective: To monitor the Phase I clinical trials of the 180-day NET microcapsule system.

PARFR-225UAB Charles E. Flowers, Jr., M.D. and Lee R. Beck, Ph.D.
University of Alabama in Birmingham
Birmingham, Alabama

Period: 4/1/81-6/30/82 Expended: \$12,825

180-Day NET Microcapsule

RESULTS: Studies have been completed. Data collection and RIA are currently being analyzed by the Principal Investigator.

Title: "Poly (lactide-co-glycolide) Norethisterone Microcapsule Study (Poly NET 90)"

Objective: To perform drug release studies and Phase I use effectiveness study of a new 90-day injectable contraceptive system.

PARFR-300 Charles E. Flowers, Jr., M.D. and Lee R. Beck, Ph.D.
University of Alabama in Birmingham
Birmingham, Alabama

Period: 8/1/81-7/31/82 Budget: \$72,984

Poly NET 90

RESULTS: Initiation of the data collection instrument study and completion of the drug preparation solvent will be accomplished in the five clinical sites by late summer 1982.

Title: "Studies on Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implants"

Objective: To perform drug release studies and a use effectiveness study of a fused norethindrone pellet.

PARFR-229B Elsimar M. Coutinho, M.D.
Maternidade Climerio de Oliveira
Salvador, Bahia, Brasil

Period: 3/1/81-6/30/82 Budget: \$32,461

PARFR-229M Roberta Rivera, M.D.
Instituto de Investigacion Cientifica
Durango, Mexico

Period: 3/1/81-6/30/82 Expended: \$35,692.27

PARFR-301C Horacio B. Croxatto, M.D.
Centro Nacional de la Familia
Santiago, Chile

Period: 11/1/81-10/31/82 Budget: \$31,476

PARFR-301T Ricardo H. Asch, M.D.
The University of Texas Health Science Center at San Antonio
San Antonio, Texas

Period: 9/1/81-8/31/82 Budget: \$39,489

NET-fused Pellets
RESULTS:

Two fused pellets releasing 74 ± 5.2 (SE) ug per day of NET fairly constantly over a period of 11-12 months, were inserted in the forearm of 50 women at Cornell and 4 other centers; i.e., San Antonio, Brazil, Mexico and Chile. Serial blood samples were obtained and serum levels of NET, FSH, LH, E₂ and P were studied.

Results were available from 3 centers for evaluation. These included data obtained at Cornell, Brazil and Mexico.

Examination of available data indicated that NET blood levels of 0.5 and 1 ng/ml were reached following insertion of pellets. There was relatively little variation over a period of up to 360 days. A very gradual decline of blood level of NET was however observed at the end of their period. Approximately 60% of cycles appeared to be ovulatory (with ovulation defined as the rise of serum P above 5 ng/ml).

The frequency of cycle control and breakthrough bleeding were acceptable. Two documented pregnancies, thus far, have been reported, both from Brazil.

Title: "Baboon Studies to Evaluate Non-Biodegradable Medicated Fibers for the Controlled-release of Contraceptive Steroids Related to Research Supported under PARFR-206SRI"

Objective: To evaluate, in vivo, progesterone-releasing fibers as potential systems for contraception in the female.

PARFR-235UAB/
 206UAB

Lee R. Beck, Ph.D.
 University of Alabama in Birmingham
 Birmingham, Alabama

Period: 4/1/81-6/30/82 Budget: \$29,789
 11/1/79-10/31/80 Expended: 18,865 (206UAB)

RESULTS: The following results of additional in vitro and in vivo studies with coaxial fibers designed to release norgestimate (NGM) and the effects of in vivo release of NGM on the baboon endometrium are in addition to results outlined in the technical report submitted previously.

The continuation of in vitro studies with the coaxial fibers prepared with a new coaxial spinneret showed that variations in the sheath-to-core ratios of the NGM-loaded fibers produced a corresponding change in release rates. The fibers with thinner membrane coatings (lower ratio) gave a faster release of drug when compared to the fibers with thicker membrane coatings (higher ratio). In all cases, the release

of NGM was essentially zero order with some slight burst effect within the first month.

Coaxial fibers retrieved from baboons treated with both intravaginal and intrauterine fibrous systems and analyzed for residual NGM showed a good correlation of in vitro to in vivo release rates for the intravaginal devices. Biopsies on animals with retained fibrous IUDs did show the effects of local NGM delivery. The intravaginal devices, consisting of NGM coaxial fibers wrapped around an elastomeric vaginal ring, were better retained in the animals during the tests (6 out of 8), and uterine biopsies from these baboons showed a definite trend of dose response.

The successful results with these prototype coaxial fibers in obtaining a constant rate of delivery of NGM and the effects of the continuous delivery of NGM from an intravaginal system on the baboon endometrium suggest that this approach could lead to a simple and practical method for self-administration of potent contraceptive steroids.

IV. SYSTEMIC CONTRACEPTION

C. OTHER

Title: "Induction of Luteolysis and Ovulation by LRF-Analogues"

Objective: To determine the effectiveness of LRF-agonist in the induction of luteolysis in the presence of luteotropic effect of exogenously administered human chorionic gonadotropin.

PARFR-228 Samuel S.C. Yen, M.D.
University of California-San Diego
La Jolla, California

Period: 4/1/81-3/31/82 Expended: \$34,977

RESULTS: Five normal cycling women were enlisted for the study. Hormone profiles during control cycle were determined for FSH, LH, estradiol and progesterone. The hormonal indices were compatible with a 28 day cycle with ovulation occurring on day 14 or 15 with normal luteal function. This was followed by a treatment cycle with LRF-agonist at 500 ug twice daily dose injected subcutaneously for 7 days. Luteolysis occurred in all LRF-agonist treatment cycles. Combined LRF-agonist and hCG administration was made during the third cycles. At the midluteal phase, human chorionic gonadotropin 5,000 IU/IM daily dose was administered for 7 days, and 2 days later, LRF-agonist cannot overcome the luteotropic effect of hCG

despite the increased dose and duration of the LRF-agonist administration.

Five postmenopausal subjects were enlisted for the study of LRF-antagonist on the inhibition of gonadotropin secretion. The administration of this LRF-antagonist at 80 ug/kg body weight injected intravenously induced a prompt decline of LH and FSH reaching a nadir approximately 3-5 hours. The recovery phase following LRF-antagonist administration appeared to follow a pulsatile secretion of LH and basal concentration reached pretreatment level 24 hours later. This finding is extremely exciting indicating that a high potent LRF-antagonist is now at hand. Consequently, studies will be designed to determine the effectiveness of this antagonist in ovulation inhibition and induction of luteolysis.

Title: "Potentially Antifertility Activity of LH/HCG Peptide Fragments"

Objective: To study in the female baboon the ability of certain unique peptides to inhibit the action of endogenously secreted gonadotropin and determine the antifertility potential of the Mckern's peptide (E₂).

PARFR-233 Joseph W. Goldzieher, M.D. and Daniel Castracane, M.D.
Southwest Foundation for Research and Education
San Antonio, Texas

Period: 4/15/81-5/14/82 Expended: \$44,086.54

RESULTS: The menstrual cycle of all baboons was followed on the basis of perineal sex skin changes and only normally cycling baboons were used in this study. Baboons at the early luteal phase (days 3-4 postovulation) or the midluteal phase

and initiated a second group of baboons at the early and mid-luteal phase. The solubility of the peptide presents no problem for such increasing dosage increments.

Title: "Studies on the Anti-Fertility Effects of a Potent LHRH Inhibitory Analog (Antagonist) in the Cynomolgus Monkey"

Objective: To determine the antifertility effects of a potent luteinizing hormone-releasing hormone inhibitory analogue (antagonist) (A-LH-RH) in the female Cynomolgus monkey (*Macaca fascicularis*). In the first section, the effects of chronic administration of A-LH-RH to normally cycling Cynomolgus monkeys will be studied. The second section deals with the administration of A-LH-Rh during the luteal phase. The third section of the study deals with the ability of A-LH-RH to interfere with the luteal production in vitro.

PARFR-302 Ricardo H. Asch, M.D.
The University of Texas Health Science Center at San Antonio
San Antonio, Texas

Period: 9/1/81-8/31/82 Budget: \$64,447

RESULTS: This project recently started, therefore, results will not be available until the next reporting period.

Title: "Ovulation Inhibition by Anordrin"

Objective: To test the efficacy of anordrin to inhibit ovulation by hormonal criteria and by direct visualization of the ovary in a primate model.

PARFR-309/209 Raksha Mehta, Ph.D.
Northwestern University Medical School
Chicago, Illinois

Period: 1/1/82-6/30/82 Budget: \$31,903
Expended: 58,261.58 (209)

RESULTS: Six adult female cynomolgus monkeys were monitored to establish the occurrence of ovulation prior to anordrin administration. Three monkeys were given anordrin intramuscularly (two animals, 4.0 mg/kg b.w.; one animal, 8.0 mg/kg b.w.) from days 9-13 of the menstrual cycle. Blood samples were collected daily at 1400 h beginning on day 10, until day 20 of the cycle by puncture of the saphenous vein. On day 17 or 19 of the cycle, laparotomy was performed on each monkey. Ovaries were observed for an ovulatory stigma, and if a cor-

pus luteum was present, it was excised for further histological examination. In this preliminary study it was found that anordrin not only had an inhibitory effect on ovulation in the cycle in which it was administered, but also had a significant inhibitory effect in several subsequent untreated months.

All 3 monkeys showed few cornified cells in their vaginal smears in the months following anordrin treatment, indicating no detectable estrogen activity following doses used. By comparison, one anovulatory monkey with polyfollicular ovaries (diagnosed by laparotomy) has abundant cornified cells in vaginal smears throughout the study. Blood progesterone levels were elevated 1-2 days after anordrin administration, but declined to low levels by day 16-17 of the cycle. In all 3 animals, the urinary pregnanediol peak was significantly lower in the anordrin treated cycles than in control cycles in the same animals. In subsequent months, no detectable pregnanediol levels were observed. Examination of the ovaries during the treatment cycles revealed no corpus luteum in one monkey, a corpus luteum with an entrapped ovum in the second, and a nonfunctional structure in the third. No menses has occurred in the three months following anordrin administration, and laparotomy 2 to 3 months after the treatment cycle has revealed ovaries without obvious follicular or luteal development. It is apparent that anordrin has an inhibitory action on ovulation probably by virtue of its antiestrogenic nature, but the dosage used in this study was too high to limit its effect to a single cycle. Based on the time course and magnitude of the effect observed, the remaining two monkeys were given anordrin on day 1 of the menstrual cycle only (4.0 mg/kg b.w. to one, 8 mg/kg b.w. to the other). At the present time these monkeys are both mid way through the treatment cycle, and laparotomies done on days 18-19 revealed no ovulation. Hormone assays have not been completed on these monkeys yet.

IV. SYSTEMIC CONTRACEPTION

C. OTHER

1. MALE PHARMACOLOGICAL METHODS

Title: "Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase-C₄"

Objective: To develop a contraceptive vaccine consisting of a synthesizable antigenic peptide that will provide antibodies against the LDH-C₄ enzyme of spermatozoa.

PARFR-315/232

Erwin Goldberg, Ph.D.
Northwestern University
Evanston, Illinois

Period: 3/1/82-2/28/83 Budget: \$53,736
 3/1/81-3/15/82 Expended: 60,018 (232)

PARFR-315/232
RESULTS:

Four peptides fragments of LDH-C₄ which bind antibody to the native protein, have been isolated by HPLC from tryptic digests. Each of these peptides has been subjected to sequence analysis and placed in the overall sequence of LDH-C₄. Two of these peptides representing residues 5-16 and residues 211-220 were selected for custom synthesis by Peninsula Laboratories, Inc.

The synthetic product will be conjugated to BSA as indicated in the proposal, and tested for immunogenicity. The peptides have proven difficult to synthesize.

The peptide, T-13, will now be designated MC₁₅₂₋₁₅₉. It has been used as a model to verify the validity of this strategy for development of a synthetic antigen useful in a contraceptive vaccine. As reported previously, rabbits immunized with BSA-MC₁₅₂₋₁₅₉ produced antibody which bound to the peptide. This binding was inhibited by free peptide and by the BSA-peptide conjugate. These antibodies were purified and tested for binding to ¹²⁵I-LDH-C₄. The results show that purified anti-MC₁₅₂₋₁₅₉ does indeed bind to LDH-C₄. Furthermore, the specificity of this binding is confirmed by competition of unlabelled LDH-C₄. As expected, only a small portion of the antibodies elicited by the BSA-peptide conjugate bind to the LDH-C₄. From these data, it can be concluded that peptide MC₁₅₂₋₁₅₉ contains an antigenic determinant of LDH-C₄. Furthermore, the strategy for development of synthetic determinants which provoke an immune response to native LDH-C₄ has proven to be sound.

Title: "Retinoids and Male Contraception"

Objective: To investigate the possible use of six retinoids as effective non-toxic and reversible male contraceptives in rats.

PARFR-236IIT

Rajendra G. Mehta, Ph.D.
IIT Research Institute
Chicago, Illinois

Period: 6/1/81-6/30/82 Expended: \$61,548.66

PARFR-236IIT
RESULTS:

Three synthetic analogs of retinoic acid were tested for their influence on male reproductive physiology of rats. At nontoxic concentration none of the retinoids have any effect on the testicular structures, sperm counts or capabilities to reproduce when they were administered either intragastrically or in diet. However, 13-cis retinoic acid when administered intraperitoneally (100 mg/kg BW) affected reproductive organs resulting in small testes, histological atrophy of testicular structure and much reduced sperm counts along with some toxic effects such as reduced body weight and bone fractures. Recently it has been shown that ethyl retinamide 2-hydroxyethyl retinamide and 13-cis retinoic acid in diet at nontoxic concentration affected male reproductive organs of hamsters significantly resulting in reduced weight, weight of testes and testicular atrophy. Similarly, it has been observed that oral administration of ethyl retinamide caused reduced spermatogenesis in dogs.

V. BARRIER CONTRACEPTION

B. FEMALE

Title: "Development of Collagen Sponge Containing Spermicide and Post-Coital Testing of Collagen Sponge Diaphragm"

Objective: To develop and test a plain collagen sponge as a vaginal contraceptive.

PARFR-212(85N)/
P2 & 3

Milos Chvapil, M.D., Ph.D.
 The University of Arizona
 Tucson, Arizona

Period: 3/1/80-6/30/82	Budget: \$75,017
12/1/76-6/30/80	Expended: 97,896 (85N)
1/1/76-4/30/76	Expended: 10,329 (P2 & 3)

Title: "Clinical Trial of the Collagen Sponge As a Contraceptive"

Objective: To determine the clinical efficacy and acceptability of the collagen sponge vaginal contraceptive.

PARFR-239

Gary S. Berger, M.D.
 Center for the Advancement of Reproductive Health, Inc.
 Chapel Hill, North Carolina

Period: 6/1/81-5/31/82 Expended: \$12,944.40

PARFR 306E

John Guillebaud, M.D.
Margaret Pyke Center
London, England

Period: 10/1/81-9/30/82 Budget: \$15,515

Collagen Sponge

RESULTS:

All clinical trials were discontinued due to an unacceptably high pregnancy rate and low continuation rate. A full report, prepared by IFRP, will be available in early fall 1982.

Title:

"Development of Sperm Enzyme Inhibitors as Vaginal Contraceptives"

Objective:

To screen the vaginal contraceptive potency of the acrosin inhibitors synthesized during the previous contract period and to determine the acute toxicity (LD₅₀) of these compounds in mice. Based on the vaginal contraceptive potency and acute toxicity, the most active and least toxic compounds were to be selected for further study.

PARFR-307/204

Lourens J.D. Zaneveld, D.V.M., Ph.D.
The University of Illinois at the Medical Center
Chicago, Illinois

Period: 1/1/82-12/31/82 Budget: \$ 64,353
 10/1/79-12/31/81 Expended: 149,605 (204)

RESULTS:

In a continuing effort to develop sperm enzyme inhibitors as vaginal contraceptives, all the acrosin inhibitors that were synthesized during the previous contract period were screened for their vaginal contraceptive potency in the rabbit. The acrosin inhibitors consist of phenols approved by the FDA for human use and guanidinobenzoic acid, forming arylguanidinobenzoates. Most of the arylguanidinobenzoates actively prevented fertilization, several being very potent. Their acute toxicity (LD₅₀) was determined in mice, and all of the arylguanidinobenzoates were less toxic than nonoxynol-9. Based on their potency and toxicity, four compounds have been selected for further study. One of these can be purchased whereas Syntex agreed to synthesize the other three in large quantities so that chronic toxicity and other efficacy studies can be performed with these compounds. Two of these compounds have already been prepared.

Two patent applications have been submitted on the work that was supported by PARFR.

VI. PREGNANCY TESTS

Title: "Detection of Pregnancy in Women Before Implantation"
Objective: To test lymphocytes and sera of women attending an artificial insemination clinic and correlate rosette inhibition findings with other tests for pregnancy.

PARFR-237 Nancy J. Alexander, Ph.D.
 Medical Research Foundation of Oregon
 Portland, Oregon

Period: 6/1/81-2/28/82 Expended: \$9,314.27

RESULTS: An early pregnancy factor (EPF) that depresses maternal lymphocyte activity as early as six hours post-mating has been described in mouse sera. In human beings this factor has been described to be present in serum as little as 48 hours after mating. If workers from other laboratories were able to demonstrate that such a test can be used, this test would be very important for any studies of post-conception types of fertility regulation. The initial experiments were unsuccessful. It was decided to repeat some studies in mice since their titer of early pregnancy factor has been reported to be significantly higher than those found in sera from newly pregnant women. It was concluded that the test to evaluate EPF does not work. The existence of a factor produced and released by a newly fertilized egg should be questioned furthermore. This concern is underscored by a complete lack of morphological correlates (e.g. endoplasmic reticulum and Golgi apparatus) within a fertilized egg. No data was found support the existence of an immunosuppressive substance produced shortly after fertilization.

VII. MISCELLANEOUS

Title: "Investigation of FCE 20340 As An Anti-Fertility Agent When Administered Parenterally or Orally"

Objective: To develop a safe oral preparation that is devoid of unwanted biological activities and effective in inhibiting ovulation, ova-transport, etc. would approach the ideal. The prostaglandin FCE 20340 appears to possess at least part of the desired attributes but it must be studied further to verify its activity, safety and specificity, preparatory to clinical trial.

PARFR-303

Leonard J. Lerner, Ph.D.
 Jefferson Medical College of Thomas Jefferson University
 Philadelphia, Pennsylvania

Period: 9/1/81-7/31/82 Budget: \$35,965

RESULTS:

FCE 20340 is more potent than PGF_2 in inhibiting ovulation induced by Pregnant Mare serum in hamsters. Complete blockage of ovulation in the superovulated animal, however, has not been obtained with the dosages employed to date, although, 40% of the group of hamsters treated with 2.0 mg of FCE 20340 did not ovulate at all. Little or no inhibition of normal ovulation was obtained with FCE 20340 or PGF_2 , however, all of these groups shed fewer ova than did the control group. The number of recoverable ova in the oviducts of induced or non-induced ovulating hamsters were decreased by PGF_2 or FCE 20340 treatment. The latter compound was more potent for this activity and a dose response effect was obtained.

Doses of FCE 20340 above 0.5 mg/kg have caused severe toxic reactions such as reduction in food and water intake, diarrhea, gastrointestinal engorgement and respiratory distress.

Title:

"Evaluation of Anti-Fertility Effects of a Potent LHRH Antagonist in the Guinea Pig as a Preclinical Model"

Objectives:

1) To examine whether the administration of LHRH-AT will cause infertility in the female guinea pig. 2) To define the critical period during the estrous cycles when administration is most effective by ascertaining: a) if LHRH-AT will inhibit the spontaneous preovulatory gonadotropin surge and prevent ovulation; b) if its administration prior to ovulation will result in luteal cell insufficiency; and c) if its administration following ovulation will effectively curtail luteum function (induced luteolysis).

PARFR-304

Walter G. Weist, Ph.D.
 Washington University
 St. Louis, Missouri

Period: 9/1/81-7/31/82 Budget: \$34,952

RESULTS:

Administration of 500 ug/day of LHRH-AT extended the cycle length and blocked ovulation in 50% of the guinea pigs, whereas smaller doses had no effects. Plasma progesterone levels did not rise above 0.8 ng/ml in the anovulatory cycles. Post-treatment cycle length returned to normal spontaneously, and ovulation occurred as determined by plasma progesterone levels. Animals in which LHRH-AT failed to block ovulation had normal pregnancies in spite of continued LHRH-AT adminis-

tration, which was continued until laparotomy was performed 18 days after vaginal opening. These preliminary "dose-finding" studies indicate that LHRH-AT has the capacity to block ovulation in the guinea pig; however, doses higher than 500 ug/day may be required to block ovulation in 100% of the animals.

WORK PLANAnticipated Accomplishments

Negotiations are underway for clinical trials of the following PARFR supported developments:

- a. MCA/FEMCEPT Project - Admission for all protocols (baseline, non-radio-opaque, randomized, single application radio-opaque, two application radio-opaque) has been completed. Follow-up data is being collected in all centers. Computer facilities will be transferred from Columbia University to BioNexus, Inc. Negotiations are underway for the continuation of trials in India and the initiation of time interval protocol with the new, modified radio-opaque MCA. New data collection instruments have been developed and introduced in all studies. Discussions on the new computer load system are underway.
- b. Collagen Sponge - A Phase II multicentered clinical trial was completed and data analyzed (PARFR-239, PARFR-306E). Post-coital acceptability and testing of a bilayered collagen diaphragm containing nonoxynol-9 is almost complete (PARFR-212(85H)).
- c. The Utero-Tubal Junction Blocking Device - Clinical studies were postponed due to problems with equipment modifications.
- d. NET-fused Pellets - Patient enrollment was completed in two US centers (PARFR-229, PARFR-301T) and two LDC centers (PARFR-229B, PARFR-229M). The study is still active in one LDC center (PARFR-301C). Preliminary data has been reviewed and submitted to the FDA in order to obtain approval for a Phase II study, which would be initiated during the next reporting period.
- e. 180-day NET Microcapsules - Preparation of the microcapsules was completed; clinical studies were completed during this reporting period (PARFR-225Ma and PARFR-225B). Clinical data and RIA values will be analyzed during the next reporting period.
- f. 90-day NET Microcapsules - The principal investigator obtained an FDA-IND. During this reporting period, microcapsules were prepared and clinical trials were planned for 10 patients in five centers. It is expected that clinical data will be analyzed during the next reporting period.
- g. NET Rods - Manufacturing capabilities were located. Protocol for the drug release study was completed, center contacted and drug release study will be initiated during the next reporting period.
- h. LHRH - An LHRH study was initiated; results are not yet available. A technical report is not due until the next reporting period (PARFR-228). We plan to initiate another study with an antagonist.

Anticipated Accomplishments (cont'd)

- i. Transcutaneous Bipolar Vasectomy Techniques - Due to a high failure rate, clinical trials (PARFR-221Ba, 221Bb and 221C) were terminated. Arrangements were made for testing the equipment and redesign of the needle (PARFR-241). Once the new needle is manufactured, further clinical trials are planned.
- j. Wing Sound II - The Wing Sound II was manufactured according to the principal investigator's specifications (PARFR-230), and sent to four centers (PARFR-311C, 314E, 313E, and 322V). Clinical trials were initiated and a preliminary report will be forthcoming in the next reporting period.

Publications:

Volume 2, No. 1 entitled: "Current Status of Plant Products Reported to Inhibit Sperm" of our series, Research Frontiers in Fertility Regulation was published. Volume 2, No. 2 is planned on "Novel Peptides in Ovarian Follicular Fluid: Implications for Contraceptive Development" and has been submitted for editorializing and publication in the next reporting period. Volume 2, No. 3 is planned on "New Developments in Spermicidal Agents, Sperm-Immobilizing Agents and Sperm Enzyme Agents."

Procedures and Activities

- 1) The scheduled Scientific Advisory Committee meeting for the next reporting period is: October 17, 1982 at the Hotel Californian in San Francisco.
- 2) PARFR's next workshop on Long-Acting Contraceptive Delivery Systems is planned for May 31 - June 3, 1983 at the International Hotel in New Orleans.

SUMMARY FINANCIAL REPORTS

This section includes:

- A. DPE-0546-A-00-1003-00 Monthly Financial Reports, 1/1/82-6/30/82
- B. AID/DSPE-C-0035 Monthly Financial Reports, 1/1/82-6/30/82
- C. AID/csd-3608 Revised Final Financial Report
- D. DPE-0546-A-00-1003-00 Subagreements, Budget and Total Expenditures When Terminated
- E. AID/DSPE-C-0035 Subcontracts, Budget and Total Expenditures When Terminated
- F. AID/csd-3608 Subcontracts, Budget and Total Expenditures When Terminated
- G. LDC Research Funds, Budget and Expenditures

	<u>AID/csd-3608</u> <u>(7/1/75-6/30/80)</u>	<u>AID/DSPE-C-0035</u> <u>(7/1/79-6/30/82)</u>	<u>DPE-0546-A-00-1003-00</u> <u>(7/1/81-6/30/86)</u>
Expenditures this period	\$ - 0 -	\$ 399,626.04	\$ 448,582.84
Expenditures through 12/31/81	<u>4,331,521.82</u>	<u>2,866,891.28</u>	<u>201,345.38</u>
Total Expenditures	\$4,331,521.82	\$3,266,517.32	\$ 649,928.22
Total Commitments	- 0 -	134,545.74	514,723.06
Uncommitted Balance	<u>180,990.68</u>	<u>8,936.94</u>	<u>329,248.72</u>
Total Budget	\$4,512,512.50	\$3,410,000.00	\$1,493,900.00

		<u>BUDGET</u>	<u>EXPENDED 7/1/81- 5/31/82</u>	<u>EXPENDED 6/1/82- 6/30/82</u>	<u>TOTAL CUMULATIVE EXPENSE</u>	<u>OUTSTANDING COMMITMENTS</u>	<u>BALANCE</u>
Salaries	02	\$167,500	\$129,031.10	\$13,302.50	\$142,333.60	\$23,900.48	\$ 1,265.92
	03	<u>83,000</u>	<u>37,924.69</u>	<u>3,536.50</u>	<u>41,461.19</u>	<u>7,215.84</u>	<u>34,322.97</u>
Total Salaries		250,500	166,955.79	16,839.00	183,794.79	31,116.32	35,588.89
Fringe Benefits	13	37,826	25,374.32	2,526.88	28,001.20	4,794.01	5,030.79
Indirect Cost	88	97,695	82,188.31	7,646.78	89,835.09	15,413.00	(7,553.09)
Supplies	05	62,154	53,225.98	6,140.16	59,366.14	3,097.35	(309.49)
	09	3,500	3,765.78	-----	3,765.78	-----	(265.78)
	10	10,000	6,305.36	(283.05)	6,022.31	-----	3,977.69
	12	1,000	354.28	-----	354.28	-----	645.72
	78	<u>200</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>	<u>200.00</u>
Total Supplies		76,854	63,651.40	5,857.11	69,508.51	3,097.35	4,248.14
Equipment	06	4,500	1,076.25	-----	1,076.25	-----	3,423.75
Travel	07	45,000	45,904.28	2,380.04	48,284.32	1,520.00	(4,804.32)
Consultant Fees	49	19,400	10,800.05	1,300.00	12,100.05	3,083.84	4,216.11
Workshop/Publication	91	50,000	36,837.76	7,900.93	44,738.69	14,566.42	(9,305.11)
Subagrcemenst	90	872,125	120,038.73	23,055.15	143,093.88	434,132.12	294,899.00
Research Supplies	92	<u>40,000</u>	<u>24,999.44</u>	<u>4,496.00</u>	<u>29,495.44</u>	<u>7,000.00</u>	<u>3,504.56</u>
TOTAL RESEARCH		912,125	145,038.17	27,551.15	172,589.32	441,132.12	298,403.56
TOTAL WORKSHOP/PUBLICATION		50,000	36,837.76	7,900.93	44,738.69	14,566.42	(9,305.11)
TOTAL ADMINISTRATION		<u>531,775</u>	<u>395,950.40</u>	<u>36,649.81</u>	<u>432,600.21</u>	<u>59,024.52</u>	<u>40,150.27</u>
TOTAL		1,493,900	577,826.33	72,101.89	649,928.22	514,723.06	329,248.72

PARFR Financial Report, June 30, 1982
DPE-0546-A-00-1003-00 (4263-407)

		<u>BUDGET</u>	<u>EXPENDED 7/1/81- 4/30/82</u>	<u>EXPENDED 5/1/82- 5/31/82</u>	<u>TOTAL CUM. EXP.</u>	<u>OUTSTANDING COMMITMENTS</u>	<u>BALANCE</u>
Salaries	02	\$167,500	\$114,810.92	\$14,220.18	\$129,031.10	\$11,757.50	\$26,711.40
	03	<u>83,000</u>	<u>34,388.19</u>	<u>3,536.50</u>	<u>37,924.69</u>	<u>3,679.34</u>	<u>41,395.97</u>
Total Salaries		250,500	149,199.11	17,756.68	166,955.79	15,436.84	68,107.37
Fringe Benefits	13	37,826	22,604.28	2,770.04	25,374.32	2,408.15	10,043.53
Indirect Cost	88	97,695	71,303.76	10,884.55	82,188.31	13,385.80	2,120.89
Supplies	05	62,154	39,870.57	13,355.41	53,225.98	8,889.31	38.71
	09	3,500	3,765.78	----	3,765.78	----	(265.78)
	10	10,000	6,305.36	----	6,305.36	(283.05)	3,977.69
	12	1,000	354.28	----	354.28	----	645.72
	78	<u>200</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>200.00</u>
Total Supplies		76,854	50,295.99	13,355.41	63,651.40	8,606.26	4,596.34
Equipment	06	4,500	1,076.25	----	1,076.25	----	3,423.75
Travel	07	45,000	43,877.74	2,026.54	45,904.28	1,512.10	(2,416.38)
Consultant Fees	49	19,400	10,800.05	----	10,800.05	----	8,599.95
Workshop/Publication	91	50,000	18,565.09	18,272.67	36,837.76	11,794.42	1,367.82
Subagreements	90	872,125	74,965.08	45,073.65	120,038.73	457,187.27	294,899.00
Research Supplies	92	<u>40,000</u>	<u>18,306.04</u>	<u>6,693.40</u>	<u>24,999.44</u>	<u>11,496.00</u>	<u>3,504.56</u>
TOTAL RESEARCH		912,125	93,271.12	51,767.05	145,038.17	468,683.27	298,403.56
TOTAL WORKSHOP/PUBLICATION		50,000	18,565.09	18,272.67	36,837.76	11,794.42	1,367.82
TOTAL ADMINISTRATION		<u>531,775</u>	<u>349,157.18</u>	<u>46,793.22</u>	<u>395,950.40</u>	<u>41,349.15</u>	<u>94,475.45</u>
TOTAL		1,493,900	460,993.39	116,832.94	577,826.33	521,826.84	394,246.83

PARFR FINANCIAL REPORT, MAY 31, 1982
DPE-0546-A-00-1003-00 (4263-407)

		<u>BUDGET</u>	<u>EXPENDED 7/1/81- 3/31/82</u>	<u>EXPENDED 4/1/82- 4/30/82</u>	<u>TOTAL CUM. EXP. 7/1/81- 4/30/82</u>	<u>OUTSTANDING COMMITMENTS</u>	<u>BALANCE</u>
Salaries	02	\$167,500.00	\$103,302.44	\$11,508.48	\$114,810.92	\$22,283.66	\$30,405.42
	03	<u>83,000.00</u>	<u>30,851.69</u>	<u>3,536.50</u>	<u>34,388.19</u>	<u>7,215.84</u>	<u>41,395.97</u>
Total Salaries		250,500.00	134,154.13	15,044.98	149,199.11	29,499.50	71,801.39
Fringe Benefits	13	37,826.00	20,257.26	2,347.02	22,604.28	4,601.92	10,619.80
Indirect Cost	88	97,695.00	61,262.00	10,041.76	71,303.76	9,199.21	17,192.03
Supplies	05	62,154.00	34,361.40	5,509.17	39,870.57	8,417.96	13,865.47
	09	3,500.00	3,444.90	320.88	3,765.78	-----	(265.78)
	10	10,000.00	5,347.78	957.58	6,305.36	(283.05)	3,977.69
	12	1,000.00	354.28	-----	354.28	-----	645.72
	78	<u>200.00</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>	<u>-----</u>	<u>200.00</u>
Total Supplies		76,854.00	43,508.36	6,787.63	50,295.99	8,134.91	18,423.10
Equipment	06	4,500.00	1,076.25	-----	1,076.25	-----	3,423.75
Travel	07	45,000.00	37,022.45	6,855.29	43,877.74	1,286.36	(164.10)
Consultant Fees	49	19,400.00	10,750.05	50.00	10,800.05	-----	8,599.95
Workshop/Publication	91	50,000.00	11,153.36	7,411.73	18,565.09	14,184.19	17,300.72
Subagreements	90	892,125.00	41,951.83	33,013.25	74,965.08	448,524.92	368,635.00
Research Supplies	92	<u>20,000.00</u>	<u>10,806.04</u>	<u>7,500.00</u>	<u>18,306.04</u>	<u>7,986.80</u>	<u>(6,292.84)</u>
TOTAL RESEARCH		912,125.00	52,757.87	40,513.25	93,271.12	456,511.72	362,342.16
TOTAL WORKSHOP/PUBL.		50,000.00	11,153.36	7,411.73	18,565.09	14,134.19	17,300.72
TOTAL ADMINISTRATION		<u>531,775.00</u>	<u>308,030.50</u>	<u>41,126.68</u>	<u>349,157.18</u>	<u>52,721.90</u>	<u>129,895.92</u>
TOTAL		1,493,900.00	371,941.73	89,051.66	460,993.39	523,367.81	509,538.80

PARFR FINANCIAL REPORT - APRIL 30, 1982
DPE-0546-A-00-1003-00 (4263-407)

SD/rsz
5/25/82

		<u>BUDGET</u> 7/1/81- 6/30/82	<u>EXPENDED</u> 7/1/81- 2/28/82	<u>EXPENDED</u> 3/1/82- 3/31/82	<u>TOTAL</u> <u>CUM. EXP.</u> 7/1/81- 3/31/82	<u>OUTSTANDING</u> <u>COMMITMENTS</u>	<u>UNCOMMITTED</u> <u>BALANCE</u>
Salaries	02	\$167,500.00	\$93,301.20	\$10,001.24	\$103,302.44	\$29,425.50	\$34,772.06
	03	<u>83,000.00</u>	<u>27,363.83</u>	<u>3,487.86</u>	<u>30,851.69</u>	<u>10,752.34</u>	<u>41,395.97</u>
Total Salaries		250,500.00	120,665.13	13,489.10	134,154.13	40,177.84	76,168.03
Fringe Benefits	13	37,826.00	18,220.41	2,036.85	20,257.26	6,066.85	11,501.89
Indirect Cost	88	97,695.00	50,854.37	10,407.63	61,262.00	12,979.28	23,453.72
Supplies	05	62,154.00	29,356.12	5,005.28	34,361.40	9,626.69	18,165.91
	09	3,500.00	3,251.74	193.16	3,444.90	----	55.10
	10	10,000.00	4,647.21	700.57	5,347.78	(227.91)	4,880.13
	12	1,000.00	354.28	----	354.28	----	645.72
	78	<u>200.00</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>200.00</u>
Total Supplies		76,854.00	37,609.35	5,899.01	43,508.36	9,398.78	23,946.86
Equipment	06	4,500.00	1,076.25	----	1,076.25	----	3,423.75
Travel	07	45,000.00	32,560.36	4,462.09	37,022.45	6,574.60	1,402.95
Consultant Fees	49	19,400.00	7,473.47	3,276.58	10,750.05	----	8,649.95
Workshop/Publications	91	50,000.00	8,780.80	2,372.56	11,153.36	10,505.77	28,340.87
Subagreements	90	892,125.00	24,170.62	17,781.21	41,951.83	465,042.17	385,131.00
Research Supplies	92	<u>20,000.00</u>	<u>10,105.54</u>	<u>700.50</u>	<u>10,806.04</u>	<u>109.80</u>	<u>9,084.16</u>
TOTAL RESEARCH		912,125.00	34,276.16	18,481.71	52,757.87	465,151.97	394,215.16
TOTAL WORKSHOP/PUBLICATIONS		50,000.00	8,780.80	2,372.56	11,153.36	10,505.77	28,340.87
TOTAL ADMINISTRATION		<u>531,775.00</u>	<u>268,459.24</u>	<u>39,571.26</u>	<u>308,030.50</u>	<u>75,197.35</u>	<u>148,547.15</u>
TOTAL		1,493,900.00	311,516.20	60,425.53	371,941.73	550,855.09	571,103.18

PARFR FINANCIAL REPORT, MARCH 31, 1982
DPE-0546-A-00-1003-00 (4263-407)

SD/rsz
4/22/82

		BUDGET 7/1/81- 6/30/82	EXPENDED 7/1/81- 1/31/82	EXPENDED 2/1/81- 2/28/82	TOTAL CUM. EXP. 7/1/81- 2/28/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	\$167,500.00	\$81,438.30	\$11,862.90	\$93,301.20	\$39,234.00	\$34,964.80
	03	<u>83,000.00</u>	<u>23,827.33</u>	<u>3,536.50</u>	<u>27,363.83</u>	<u>14,288.84</u>	<u>41,347.33</u>
Total Salaries		250,500.00	105,265.63	15,399.40	120,665.03	53,522.84	76,312.13
Fringe Benefits	13	37,826.00	15,895.10	2,325.31	18,220.41	8,081.95	11,523.64
Indirect Cost	88	97,695.00	44,412.50	6,441.87	50,854.37	16,791.21	30,049.42
Supplies	05	62,154.00	26,520.42	2,835.70	29,356.12	10,527.84	22,270.04
	09	3,500.00	3,066.35	185.39	3,251.74	----	248.26
	10	10,000.00	3,783.97	863.24	4,647.21	(227.91)	5,580.70
	12	1,000.00	354.28	----	354.28	----	645.72
	78	<u>200.00</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>200.00</u>
Total Supplies		76,854.00	33,725.02	3,884.33	37,609.35	10,299.93	28,944.72
Equipment	06	4,500.00	1,076.25	----	1,076.25	----	3,423.75
Travel	07	45,000.00	29,198.15	3,362.21	32,560.36	6,280.60	6,159.04
Consultant Fees	49	19,400.00	7,473.47	----	7,473.47	----	11,926.53
Workshop/Publ.	91	50,000.00	----	8,780.80	8,780.80	5,733.00	35,486.20
Subagreements	90	892,125.00	7,195.02	16,975.60	24,170.62	482,823.38	385,131.00
Research Supplies	92	<u>20,000.00</u>	<u>8,635.70</u>	<u>1,469.84</u>	<u>10,105.54</u>	<u>109.80</u>	<u>9,784.66</u>
TOTAL RESEARCH		912,125.00	15,830.72	18,445.44	34,276.16	482,933.18	394,915.66
TOTAL WORKSHOP/PUBL		50,000.00	----	8,780.80	8,780.80	5,733.00	35,486.20
TOTAL ADMINISTRATION		<u>531,775.00</u>	<u>237,046.12</u>	<u>31,413.12</u>	<u>268,459.24</u>	<u>94,976.53</u>	<u>168,339.23</u>
TOTAL		1,493,900.00	252,876.84	58,639.36	311,516.20	583,642.71	598,740.09

		<u>BUDGET</u> <u>7/1/81-</u> <u>6/30/82</u>	<u>EXPENDED</u> <u>7/1/81-</u> <u>12/31/81</u>	<u>EXPENDED</u> <u>1/1/82-</u> <u>1/31/82</u>	<u>TOTAL</u> <u>CUM. EXP.</u> <u>7/1/81-</u> <u>1/31/82</u>	<u>OUTSTANDING</u> <u>COMMITMENTS</u>	<u>UNCOMMITTED</u> <u>BALANCE</u>
Salaries	02	167,500.00	69,247.06	12,191.24	81,438.30	56,542.50	29,519.20
	03	<u>83,000.00</u>	<u>20,290.83</u>	<u>3,536.50</u>	<u>23,827.33</u>	<u>17,825.34</u>	<u>41,347.33</u>
Total Salaries		250,500.00	89,537.89	15,727.74	105,265.63	74,367.84	70,866.53
Fringe Benefits	13	37,826.00	13,520.21	2,374.89	15,895.10	11,229.54	10,701.36
Indirect Cost	88	97,695.00	36,093.20	8,319.30	44,412.50	21,621.09	31,661.41
Supplies	05	62,154.00	23,120.59	3,399.83	26,520.42	10,747.84	24,885.74
	09	3,500.00	3,066.35	----	3,066.35	----	433.65
	10	10,000.00	3,783.97	----	3,783.97	(227.91)	6,443.94
	12	1,000.00	354.28	----	354.28	----	645.72
	78	<u>200.00</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>----</u>	<u>200.00</u>
Total Supplies		76,854.00	30,325.19	3,399.83	33,725.02	10,519.93	32,609.05
Equipment	06	4,500.00	1,076.25	----	1,076.25	----	3,423.75
Travel	07	45,000.00	20,157.17	9,040.98	29,198.15	3,925.17	11,876.68
Consultant Fees	49	19,400.00	7,473.47	----	7,473.47	----	11,926.53
Workshop/Publ.	91	50,000.00	----	----	----	11,062.80	38,937.20
Subagreements	90	892,125.00	----	7,195.02	7,195.02	400,945.98	483,984.00
Research Supplies	92	<u>20,000.00</u>	<u>3,162.00</u>	<u>5,473.70</u>	<u>8,635.70</u>	<u>1,579.64</u>	<u>9,784.66</u>
TOTAL RESEARCH		912,125.00	3,162.00	12,668.72	15,830.72	402,525.62	493,768.66
TOTAL WORKSHOP/PUBL.		50,000.00	----	----	----	11,062.80	38,937.20
TOTAL ADMINISTRATION		<u>531,775.00</u>	<u>198,133.38</u>	<u>38,862.74</u>	<u>237,046.12</u>	<u>121,663.57</u>	<u>173,065.31</u>
TOTAL		1,493,900.00	201,345.38	51,531.46	252,876.84	535,251.99	705,771.17

PARFR Financial Report, January 31, 1982
DPE-0546-A-00-1003-00 (4263-407)

ACN/rsz
2/26/82

		BUDGET 7/1/79 6/30/81	EXPENDED 7/1/79 - 5/30/82	EXPENDED 6/1/82 - 6/30/82	TOTAL CUM. EXP. 7/1/79 6/30/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	\$310,400.00	\$301,900.73	---	\$301,900.73	---	\$ 8,499.27
	03	<u>75,534.00</u>	<u>70,363.17</u>	---	<u>70,363.17</u>	---	<u>5,370.83</u>
Total Salaries		386,134.00	372,263.90	---	372,263.90	---	13,870.10
Fringe Benefits	13	55,217.00	53,637.35	---	53,637.35	---	1,579.65
Indirect Costs	88	150,596.00	144,300.91	---	144,300.91	---	6,295.09
Supplies	05	129,100.00	142,671.35	(100.00)	142,571.35	---	(13,471.35)
	09	6,900.00	5,429.63	---	5,429.63	---	1,470.37
	10	19,700.00	16,942.52	---	16,942.52	---	2,757.48
	12	2,200.00	2,157.42	---	2,157.42	---	42.58
	78	<u>400.00</u>	<u>240.44</u>	---	<u>240.44</u>	---	<u>159.56</u>
Total Supplies		158,300.00	167,441.36	(100.00)	167,341.36	---	(9,041.36)
Equipment	06	2,100.00	4,734.79	---	4,734.79	---	(2,634.79)
Consultant Fees	4	35,200.00	35,245.40	---	35,245.40	---	(45.40)
Travel	07	115,000.00	116,533.80	---	116,533.80	---	(1,533.80)
Workshop/Publication	91	135,000.00	154,421.63	111.00	154,532.63	---	(19,532.63)
Subcontracts	90	2,262,453.00	2,082,796.60	19,189.54	2,101,986.14	134,545.74	25,921.12
Pilot Studies	92	<u>110,000.00</u>	<u>115,941.04</u>	---	<u>115,941.04</u>	---	<u>(5,941.04)</u>
TOTAL RESEARCH		2,372,453.00	2,198,737.64	19,189.54	2,217,927.18	134,545.74	19,980.08
TOTAL WORKSHOP/PUBLICATION		135,000.00	154,421.63	111.00	154,532.63	00	(19,532.63)
TOTAL ADMINISTRATION		<u>902,547.00</u>	<u>894,157.51</u>	<u>(100.00)</u>	<u>894,057.51</u>	<u>00</u>	<u>8,489.49</u>
TOTAL		3,410,000.00	3,247,316.78	19,200.54	3,266,517.32	134,545.74	8,936.94

PARFR FINANCIAL REPORT, JUNE 30, 1982
AID DSPE-C-0035 (4263-404)

		BUDGET 7/1/79- 6/30/81	EXPENDED 7/1/79- 4/30/82	EXPENDED 5/1/82- 5/31/82	TOTAL CUM. EXP. 7/1/79- 5/31/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	\$310,400	\$301,900.73	----	\$301,900.73	----	\$ 8,499.27
	03	<u>75,534</u>	<u>70,363.17</u>	----	<u>70,363.17</u>	----	<u>5,370.83</u>
Total Salaries		386,134	372,263.90	----	372,263.90	----	13,870.10
Fringe Benefits	13	55,217	53,637.35	----	53,637.35	----	1,579.65
Indirect Costs	88	150,596	144,300.91	----	144,300.91	----	6,295.09
Supplies	05	129,100	142,656.93	14.42	142,671.35	117.18	(13,688.53)
	09	6,900	5,429.63	----	5,429.63	----	1,470.37
	10	19,700	16,942.52	----	16,942.52	----	2,757.48
	12	2,200	2,157.42	----	2,157.42	----	42.58
	78	<u>400</u>	<u>240.44</u>	----	<u>240.44</u>	----	<u>159.56</u>
Total Supplies		158,300	167,426.94	14.42	167,441.36	117.18	(9,258.54)
Equipment	06	2,100	4,734.79	----	4,734.79	----	(2,634.79)
Consultant Fees	49	35,200	35,245.40	----	35,245.40	----	(45.40)
Travel	07	115,000	116,533.80	----	116,533.80	----	(1,533.80)
Workshop/Publication	91	135,000	140,921.63	13,500.00	154,421.63	215.00	(19,636.63)
Subcontracts	90	2,262,453	2,003,863.94	78,932.66	2,082,796.60	152,564.09	27,092.31
Pilot Studies	92	<u>110,000</u>	<u>115,941.04</u>	----	<u>115,941.04</u>	----	<u>(5,941.04)</u>
TOTAL RESEARCH		2,372,453	2,119,804.98	78,932.66	2,198,737.64	152,564.09	21,151.27
TOTAL WORKSHOP/PUBLICATION		135,000	140,921.63	13,500.00	154,421.63	215.00	(19,636.63)
TOTAL ADMINISTRATION		<u>902,547</u>	<u>894,143.09</u>	<u>14.42</u>	<u>894,157.51</u>	<u>117.18</u>	<u>8,272.31</u>
TOTAL		3,410,000	3,154,869.70	92,447.08	3,247,316.78	152,896.27	9,786.95

PARFR FINANCIAL REPORT, MAY 31, 1982
AID DSPE-C-0035 (4263-404)

		BUDGET 7/1/79- 6/30/81	EXPENDED 7/1/79- 3/31/82	EXPENDED 4/1/82- 4/30/82	TOTAL CUM. EXP. 7/1/79- 4/30/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	\$310,400.00	\$301,900.73	----	\$301,900.73	----	\$ 8,499.27
	03	<u>75,534.00</u>	<u>70,363.17</u>	----	<u>70,363.17</u>	----	<u>5,370.83</u>
Total Salaries		386,134.00	372,263.90	----	372,263.90	----	13,870.10
Fringe Benefits	13	55,217.00	53,637.35	----	53,637.35	----	1,579.65
Indirect Costs	88	150,596.00	144,300.91	----	144,300.91	----	6,295.09
Supplies	05	129,100.00	142,656.93	----	142,656.93	413.23	(13,970.16)
	09	6,900.00	5,429.63	----	5,429.63	----	1,470.37
	10	19,700.00	16,942.52	----	16,942.52	----	2,757.48
	12	2,200.00	2,157.42	----	2,157.42	----	42.58
	78	<u>400.00</u>	<u>240.44</u>	----	<u>240.44</u>	----	<u>159.56</u>
Total Supplies		158,300.00	167,426.94	----	167,426.94	413.23	(9,540.17)
Equipment	06	2,100.00	4,734.79	----	4,734.79	----	(2,634.79)
Consultant Fees	49	35,200.00	35,245.40	----	35,245.40	----	(45.40)
Travel	07	115,000.00	116,533.80	----	116,533.80	----	(1,533.80)
Workshop/Publication	91	135,000.00	140,921.63	----	140,921.63	13,715.00	(19,636.63)
Subcontracts	90	2,262,453.00	1,968,044.62	35,819.32	2,003,863.94	232,271.60	26,317.46
Pilot Studies	92	<u>110,000.00</u>	<u>115,941.04</u>	----	<u>115,941.04</u>	----	<u>(5,941.04)</u>
TOTAL RESEARCH		2,372,453.00	2,083,985.66	35,819.32	2,119,804.98	232,271.60	20,376.42
TOTAL WORKSHOP/PUBL.		135,000.00	140,921.63	----	140,921.63	13,715.00	(19,636.63)
TOTAL ADMINISTRATION		<u>902,547.00</u>	<u>894,143.09</u>	----	<u>894,143.09</u>	<u>413.23</u>	<u>7,990.68</u>
TOTAL		3,410,000.00	3,119,050.38	35,819.32	3,154,869.70	246,399.83	8,730.47

PARFR FINANCIAL REPORT, APRIL 30, 1982
AID DSPE-C-0035 (4263-404)

		BUDGET 7/1/79- 6/30/81	EXPENDED 7/1/79- 2/28/82	EXPENDED 3/1/81- 3/31/82	TOTAL CUM. EXP. 7/1/79- 3/31/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	\$310,400.00	\$301,900.73	-----	\$301,900.73	-----	\$ 8,499.27
	03	<u>75,734.00</u>	<u>70,363.17</u>	-----	<u>70,363.17</u>	-----	<u>5,370.83</u>
Total Salaries		386,134.00	372,263.90	-----	372,263.90	-----	13,870.10
Fringe Benefits	13	55,217.00	53,637.35	-----	53,637.35	-----	1,579.65
Indirect Cost	88	150,596.00	144,300.91	-----	144,300.91	-----	6,295.09
Supplies	05	129,100.00	142,656.93	-----	142,656.93	413.23	(13,970.16)
	09	6,900.00	5,429.63	-----	5,429.63	-----	1,470.37
	10	19,700.00	16,942.52	-----	16,942.52	-----	2,757.48
	12	2,200.00	2,157.42	-----	2,157.42	-----	42.58
	78	<u>400.00</u>	<u>240.44</u>	-----	<u>240.44</u>	-----	<u>159.56</u>
Total Supplies		158,300.00	167,426.94	-----	167,426.94	413.23	(9,540.17)
Equipment	06	2,100.00	1,187.79	3,547.00	4,734.79	-----	(2,634.79)
Consultant Fees	49	35,200.00	35,245.40	-----	35,245.40	-----	(45.40)
Travel	07	115,000.00	116,533.80	-----	116,533.80	-----	(1,533.80)
Workshop/Publication	91	135,000.00	140,921.63	-----	140,921.63	13,715.00	(19,636.63)
Subcontracts	90	2,262,453.00	1,843,454.58	124,590.04	1,968,044.62	287,965.95	6,442.43
Pilot Studies	92	<u>110,000.00</u>	<u>114,568.06</u>	<u>1,372.98</u>	<u>115,941.04</u>	<u>362.53</u>	<u>(6,303.57)</u>
TOTAL RESEARCH		2,372,453.00	1,958,022.64	125,963.02	2,083,985.66	288,328.48	(138.86)
TOTAL WORKSHOP/PUBLI.		135,000.00	140,921.63	-----	140,921.63	13,715.00	(19,636.63)
TOTAL ADMINISTRATION		<u>902,547.00</u>	<u>890,596.09</u>	<u>3,547.00</u>	<u>894,143.09</u>	<u>413.23</u>	<u>7,990.68</u>
TOTAL		3,410,000.00	2,989,540.36	129,510.02	3,119,050.38	302,456.71	(11,507.09)

PARFR FINANCIAL REPORT, MARCH 31, 1982
AID DSPE-C-0035 (4263-404)

		BUDGET 7/1/79- 6/30/81	EXPENDED 7/1/79- 1/31/82	EXPENDED 2-1-82- 2/28/82	TOTAL CUM. EXP. 7/1/79- 2/28/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	310,400.00	301,900.73	.00	301,900.73	.00	8,499.27
	03	<u>75,734.00</u>	<u>70,363.17</u>	<u>.00</u>	<u>70,363.17</u>	<u>.00</u>	<u>5,370.83</u>
Total Salaries		386,134.00	372,263.90	.00	372,263.90	.00	13,870.10
Fringe Benefits	13	55,217.00	53,637.35	.00	53,637.35	.00	1,579.65
Indirect Cost	88	150,596.00	144,300.91	.00	144,300.91	.00	6,295.09
Supplies	05	129,100.00	142,656.93	.00	142,656.93	413.23	(13,970.16)
	09	6,900.00	5,429.63	.00	5,429.63	.00	1,470.37
	10	19,700.00	16,942.52	.00	16,942.52	.00	2,757.48
	12	2,200.00	2,157.42	.00	2,157.42	.00	42.58
	78	<u>400.00</u>	<u>240.44</u>	<u>.00</u>	<u>240.44</u>	<u>.00</u>	<u>159.56</u>
Total Supplies		158,300.00	167,426.94	.00	167,426.94	413.23	(9,540.17)
Equipment	06	2,100.00	551.50	636.29	1,187.79	3,535.00	(2,622.79)
Consultant Fees	49	35,200.00	35,245.40	.00	35,245.40	.00	(45.40)
Travel	07	115,000.00	116,533.80	.00	116,533.80	.00	(1,533.80)
Workshop/Publ.	91	135,000.00	140,921.63	.00	140,921.63	13,715.00	(19,636.63)
Subcontracts	90	2,262,453.00	1,769,586.51	73,868.07	1,843,454.58	413,982.98	5,015.44
Pilot Studies	92	<u>110,000.00</u>	<u>107,230.64</u>	<u>7,337.42</u>	<u>114,568.06</u>	<u>1,829.60</u>	<u>(6,397.66)</u>
TOTAL RESEARCH		2,372,453.00	1,876,817.15	81,205.49	1,958,022.64	415,812.58	(1,382.22)
TOTAL WORKSHOP/PUBL.		135,000.00	140,921.63	.00	140,921.63	13,715.00	(19,636.63)
TOTAL ADMINISTRATION		<u>902,547.00</u>	<u>889,959.80</u>	<u>636.29</u>	<u>890,596.09</u>	<u>3,948.23</u>	<u>8,002.68</u>
TOTAL		3,410,000.00	2,907,698.58	81,841.78	2,989,540.36	433,475.81	(13,016.17)

PARFR Financial Report, February 28, 1982
AID/DSPE-C-0035 (4263-404)

		BUDGET 7/1/79- 6/30/81	EXPENDED 7/1/79- 12/31/81	EXPENDED 1/1/82- 1/31/82	TOTAL CUM. EXP. 7/1/79- 1/31/82	OUTSTANDING COMMITMENTS	UNCOMMITTED BALANCE
Salaries	02	310,400.00	301,900.73	----	301,900.73	----	8,499.27
	03	<u>75,734.00</u>	<u>70,363.17</u>	----	<u>70,363.17</u>	----	<u>5,370.83</u>
Total Salaries		386,134.00	372,263.90	----	372,263.90	----	13,870.10
Fringe Benefits	13	55,217.00	53,637.35	----	53,637.35	----	1,579.65
Indirect Cost	88	150,596.00	144,300.91	----	144,300.91	----	6,295.09
Supplies	05	129,100.00	142,656.93	----	142,656.93	413.23	(13,970.16)
	09	6,900.00	5,429.63	----	5,429.63	----	1,470.37
	10	19,700.00	16,942.52	----	16,942.52	----	2,757.48
	12	2,200.00	2,157.42	----	2,157.42	----	42.58
	78	<u>400.00</u>	<u>240.44</u>	----	<u>240.44</u>	----	<u>159.56</u>
Total Supplies		158,300.00	167,426.94	----	167,426.94	413.23	(9,540.17)
Equipment	06	2,100.00	551.50	----	551.50	4,149.23	(2,600.73)
Consultant Fees	49	35,200.00	35,245.40	----	35,245.40	----	(45.40)
Travel	07	115,000.00	116,533.80	----	116,533.80	----	(1,533.80)
Workshop/Publ.	91	135,000.00	140,921.63	----	140,921.63	13,715.00	(19,636.63)
Subcontracts	90	2,262,453.00	1,728,779.21	40,807.30	1,769,586.51	489,208.85	3,657.64
Pilot Studies	92	<u>110,000.00</u>	<u>107,230.64</u>	----	<u>107,230.64</u>	<u>9,167.16</u>	<u>(6,397.80)</u>
TOTAL RESEARCH		2,372,453.00	1,836,009.85	40,807.30	1,876,817.15	498,376.01	(2,740.16)
TOTAL WORKSHOP/PUBL.		135,000.00	140,921.63	----	140,921.63	13,715.00	(19,636.63)
TOTAL ADMINISTRATION		<u>902,547.00</u>	<u>889,959.80</u>	----	<u>889,959.80</u>	<u>4,562.46</u>	<u>8,024.74</u>
		3,410,000.00	2,866,891.28	40,807.30	2,907,698.58	516,653.47	(14,352.05)

PARFR FINANCIAL REPORT, JANUARY 31, 1982
AID/DSPE-C-0035 (4263-404)

		Budget 7/1/75- 6/30/80	Expended 7/1/75- 12/31/81	Expended 1/1/82- 6/30/82	Total Cum. Exp. 7/1/75 - 6/30/82	Outstanding Commits Through 6/30/80	Balance
Salaries	02	269,218.89	269,218.89	---	269,218.89	---	---
	03	103,708.02	103,708.02	---	103,708.02	---	---
TOTAL SALARIES		372,926.91	372,926.91	---	372,926.91	---	---
Fringe Benefits	13	51,269.43	51,269.43	---	51,269.43	---	---
Indirect Costs	88	131,094.58	131,094.58	---	131,094.58	---	---
Supplies	05	131,925.54	131,925.54	---	131,925.54	---	---
	09	527.81	527.81	---	527.81	---	---
	10	5,931.81	5,931.81	---	5,931.81	---	---
	12	1,591.00	1,591.00	---	1,591.00	---	---
	78	1,567.39	1,567.39	---	1,567.39	---	---
TOTAL SUPPLIES		141,543.55	141,543.55	---	141,543.55	---	---
Equipment	06	27,995.16	27,995.16	---	27,995.16	---	---
Consulting Fees	49	40,973.11	40,973.11	---	40,973.11	---	---
Travel	07	143,860.20	143,860.20	---	143,860.20	---	---
Moving Expense	18	2,963.91	2,963.91	---	2,963.91	---	---
Remodl. & Maint.	52	11,249.30	11,249.30	---	11,249.30	---	---
Wkshop/Publ.	91	192,352.77	191,662.77	---	191,662.77	---	690.00
Subcontracts	90	3,253,038.11	3,092,337.24	---	3,092,337.24	---	160,700.87
Pilot Studies	92	143,245.47	123,645.66	---	123,645.66	---	19,599.91
TOTAL RESEARCH		3,396,283.58	3,215,982.90	---	3,215,982.90	---	180,300.68
TOTAL WORKSHOP		192,352.77	191,662.77	---	191,662.77	---	690.00
TOTAL ADMINISTRATION		923,876.15	923,876.15	---	923,876.15	---	---
TOTAL		4,512,512.50	4,331,521.82	---	4,331,521.82	---	180,990.68

PARFR Financial Report, Revised Final
(Funds Committed prior to 6/30/80)
AID/csd-3608 (4263-401)

PARFR/NORTHWESTERN UNIVERSITY

COOPERATIVE AGREEMENT: DPE-0546-A-00-1003-00
7/1/81-6/30/82

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR(S)</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
300	University of Alabama in Birmingham Birmingham, Alabama	Charles E. Flowers, Jr., M.D. Lee R. Beck, Ph.D.	"Poly (lactide-co-glycolide) Norethisterone Microcapsule Study (Poly NET 90)"	8/1/81- 7/31/82	\$ 72,984	
301C	Centro Nacional de la Familia (CENFA) Santiago, Chile	Horacio B. Croxatto, M.D.	"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant"	11/1/81- 10/31/82	31,476	
301T	The University of Texas Health Science Center at San Antonio	Ricardo H. Asch, M.D.	(SAME AS ABOVE)	9/1/81- 8/31/82	39,489	
302	The University of Texas Health Science Center at San Antonio	Ricardo H. Asch, M.D.	"Studies on the Anti-Fertility Effects of a Potent LHRH Inhibitory Analog (Antagonist) in the Cynomologus Monkey"	9/1/81- 8/31/82	64,447	
303	Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania	Leonard J. Lerner, Ph.D.	"Investigation of FC 20340 As An Anti-Fertility Agent When Administered Parenterally or Orally"	9/1/81- 8/31/82	35,695	
304	Washington University St. Louis, Missouri	Walter G. Wiersb, Ph.D. Chander P. Puri, Ph.D.	"Evaluation of Anti-Fertility Effects of a Potent LHRH Antagonist in the Guinea Pig as a Preclinical Model"	9/1/81- 7/31/82	34,952	

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305V	Maternidad "Concepcion Palacios" Caracas, Venezuela	Itic Zigelboim, M.D. Wiktor Szczedrin, M.D.	"Radio-Opaque Methylcyanoacrylate (MCA) Delivered Through Single Application (FEMCEPT) Device"	9/10/81- 9/9/82	\$ 17,225	
306E	Margaret Pyke Centre London, England	John Guillebaud, M.D.	"Clinical Trial of the Collagen Sponge as a Contraceptive"	10/1/81- 9/30/82	15,515	
307	University of Illinois at the Medical Center Chicago, Illinois	Lourens J.D. Zaneveld D.V.M., Ph.D.	"Development of Sperm Enzyme Inhibitors as Vaginal Contraceptives - Continuation of PARFR-204"	1/1/82- 12/31/82	64,353	
308	Tulane University Covington, Louisiana	Ronald W. Lewis, M.D.	"Transcutaneous Ablation of Cauda Epididymis in Non-Human Primates"	1/1/82 12/31/82	39,595	
309	Northwestern University Medical School Chicago, Illinois	Raksha Mehta, Ph.D.	"Ovulation Inhibition by Anordrin"	1/1/82- 6/30/82	31,903	
310C	Enrique Guiloff, M.D. Santiago, Chile	Enrique Guiloff, M.D.	"MCA/FEMCEPT Video Study"	1/1/82- 6/30/83	8,000	
311C	Universidad Austral de Chile Valdivia, Chile	Rene Guzman-Serani, M.D.	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)"	3/1/82- 8/31/83	7,500	

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312	The Cornell University Medical College New York, New York	Brij B. Saxena, Ph.D., D.Sc. Gopi N. Gupta, Ph.D. William J. Ledger, M.D.	"A Clinical Evaluation of the Subdermal Contracep- tive Norethindrone Pellet - Continuation of PARFR-229"	1/1/82- 7/31/82	\$ 33,356	
313E	Institute of Population Studies, University of Exeter Devon, England	Robert Snowden, Ph.D.	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)"	2/1/82- 7/31/83	21,600	
314E	Shatby Hospital The University of Alexandria Alexandria, Egypt	Mokhtar Toppozada, M.D.	"Uterine Measurement - Clinical Comparison Study (Wing Sound II)"	2/1/82- 7/31/83	5,400	
315	Northwestern University Evanston, Illinois	Erwin Goldberg, Ph.D.	"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Dehydrogenase-C ₄ - Exten- sion of PARFR-232	3/1/82- 2/28/83	53,736	
316C	Universidad de Austral de Chile Valdivia, Chile	Rene Guzman-Serani, M.D.	"MCA/FEMCEPT Study"	4/1/82- 3/31/84	24,000	
318B	Maternidade Climerio de Oliveira Salvador, Bahia, Brasil	Elsimar M. Coutinho, M.D.	"MCA/FEMCEPT Study"	5/1/82- 4/30/83	14,982	

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DIRECT PAYMENTS RELATED TO PARFR APPROVED SUBAGREEMENTS
 Account: 4263-407-90 (92) -- Agreement: DPE-0546-A-00-1003-00

PARFR #	PAYEE	RELATES TO	BUDGET	AMOUNT PAID
D-20	The University of Illinois at the Medical Center (BRL) Req. #7782, #5806, #5810	Zaneveld Quinacrine Pig Study	\$10,000	\$ 5,332.34
	Lourens J.D. Zaneveld, D.V.M., Ph.D. Req. #7791	10/16/81-12/18/81 Consultation - Quinacrine Pig Study	----	4,818.50
D-21	American Scientific Products Req. #7769, #5890	India-ICMR - Radio-Opaque MCA/FEMCEPT Study	----	1,201.80
D-22	The University of Alabama in Birmingham c/o Dr. Lee Beck Req. #2467	UAB Continuation of PARFR-214(83N) - Final Report Due 5/31/82	8,000	-----
D-23	The University of Illinois at the Medical Center (BRL) Req. #2406 (BRL), #2488 (BRL)	Ecballium Elaterium	1,745	726.60
D-24	Southern Research Institute Req. #5880	Liability Insurance Premium to Produce Microcapsules for 50 Patients (PARFR-300)	7,500	7,500
D-25	Reznik Instruments, Inc. Req. #5894	Development and Manufacture of 3 Bipolar Needles	550	550
D-26	Connaught Laboratories Req. #5886	20 Vials of Diptheria Toxoid (PARFR-315 Goldberg) Carrier for Immunizing Baboons (U of I)	2,000	-----
D-27	Peninsula Laboratories, Inc. Req. #5893	500 mg. Peptide for Goldberg/U of I	5,000	

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 Account: 4263-407-90 (92) -- Agreement: DPE-0546-A-00-1003-00

<u>PARFR #</u>	<u>PAYEE</u>	<u>RELATES TO</u>	<u>BUDGET</u>	<u>AMOUNT PAID</u>
D-28	The Johns Hopkins University Req. #2411	Quinacrine analysis of pig tissues 165 samples at \$12/sample	1,980	1,980
D-29	University of Arizona Req. #2416	Purchase of 2,000 Collagen Sponges	3,000	3,000
D-30	PIACT Req. #2419	P.O. - PIACT Testing of New Needle to use with Aspen Power Supply purchased under PARFR-221C	4,496	4,496

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200C	Columbia University New York, New York	Ralph M. Richart, M.D.	"Data Collection and Analysis for MCA/FEMCEPT Clinical Trials"	7/1/79- 6/30/81	\$35,832.67	\$35,570.14
200G	Bureau Mengen Cologne, West Germany (Continuation of PARFR-86G)	Hans Baur, M.D.	"Phase I Clinical Trial of Fallopian Tube Closure Using Methylcyanoacrylate (MCA) Tissue Adhesive Delivered Through the Single-Application Fertility Regulation (FEMCEPT) Device"	9/1/79- 8/31/80	32,020	24,478.41
200K	Korea University College of Medicine Seoul, Korea	Sung-bong Hong, M.D. C-I Soo Cong Lee, M.D.	(SAME AS ABOVE)	5/1/80- 8/31/82	2,598	
200P	JFMH Comprehensive Family Planning Center Manila, Philippines	Ruben A. Apelo, M.D.	(SAME AS ABOVE)	10/1/79- 6/30/82	14,385	
201B	Maternidade Climerio de Oliveira Salvador, Bahia, Brasil	Hugo Maia, Jr., M.D.	"Effect of LH-RH Agonist on Ovulation and Corpus Luteum Function in Women"	8/1/79- 11/30/80	34,600	34,600
202	Texas Tech University Lubbock, Texas	M. W. Heine, M.D.	"Collagen Sponge Contraceptive -- Testing of Efficacy in Human Volunteers"	9/1/79- 12/31/80	49,044	37,336.33
203NU	Northwestern University Evanston, Illinois	Robert T. Chatterton, Ph.D.	"Fertility Regulation by Control of Progesterone Clearance"	9/1/79- 12/31/81	92,535	
203NMH	Northwestern Memorial Hospital Chicago, Illinois	Robert T. Chatterton, Ph.D.	(SAME AS ABOVE)	9/1/79- 12/31/81	48,636	48,636

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203IIT	IIT Research Institute Chicago, Illinois	Kurt Gutfreund	"Microencapsulation of Progesterone Antibodies"	11/1/79- 6/30/81	\$ 21,905	\$ 20,478.94
204	University of Illinois at the Medical Center Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D.	"Development of Sperm Enzyme Inhibitors as Vaginal Contraceptives"	10/1/79- 12/31/81	149,605	
205(95N)	University of Illinois at the Medical Center Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D.	"Development and Evaluation of a Reversible Vas Deferens Blocking Device"	10/1/79- 12/31/81	108,548	108,548
206UAB	University of Alabama in Birmingham, Birmingham, Alabama	Lee R. Beck, Ph.D.	"Baboon Studies to Evaluate Non-Biodegradable Medicated Fibers for the Controlled-Release of Contraceptive Steroids Related to Research Supported under PARFR-206SRI"	11/1/79- 10/31/80	18,865	18,865
206SRI	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the Female Reproductive Tract"	11/1/79- 12/31/80	66,000	65,091.53
207	Hektoen Institute for Medical Research Chicago, Illinois	Abdol H. Hosseinian, M.D.	"Hysteroscopic Sterilization by Using Uterotubal Blocking Devices"	11/1/79- 6/30/82	24,348	
207M	PROJECT NEVER STARTED -----					
208	University of Alabama in Birmingham Birmingham, Alabama	Lee R. Beck, Ph.D.	"Testing the Abortifacient Potential of CI and CII, 1 Beta-Oh Androstane Derivatives, in the Baboon"	11/1/79- 1/31/81	27,358	27,323.94

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209NU	Northwestern University Evanston, Illinois	Raksha Mehta, Ph.D.	"Evaluation of A-Nor Steroids as Potential Once-A-Month Contraceptive Agents"	1/1/80- 12/31/81	\$ 58,741	\$ 58,261.68
209NMH	Northwestern Memorial Hospital Chicago, Illinois	Raksha Mehta, Ph.D.	(SAME AS ABOVE)	1/1/80- 12/31/81	51,299	51,299
210	Worcester Foundation for Experimental Biology Shrewsbury, Massachusetts	M. C. Chang, Ph.D.	"Study of a Plant Product 'Gossypol' as a Reversible Contraceptive in Male Rabbits"	1/1/80 3/31/81	43,070	43,070
211	-----Joseph E. Davis, M.D.----- New York, New York		"Study of Vas Occlusion in Animals Using Chemical Agents"	12/1/79- 9/30/81	13,540	13,022.70
212(85N)	The University of Arizona Health Sciences Center Tucson, Arizona	Milos Chvapil, M.D., Ph.D.	"Development of Collagen Sponge Containing Spermicide and Post-Coital Testing of Collagen Sponge Diaphragm"	3/1/80- 6/30/82	75,017	
213T	The University of Texas Health Science Center at San Antonio San Antonio, Texas	Mohammed M. Ahmad, M.D., Ph.D. and Ricardo H. Asch, M.D.	"The Study of the Intravaginal Insert (IVI) - Acceptability and Side Effects"	7/1/80- 6/30/81	14,751	
213B	PROJECT NEVER STARTED -----					

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214(83N)	University of Alabama in Birmingham Birmingham, Alabama	Lee R. Beck, Ph.D.	"Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone"	4/1/80 9/30/81	\$ 96,937	\$ 96,937
214(110N)	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"Optimization of an Injectable Microcapsule Formulation for the 90-day Delivery of Norethisterone"	4/1/80- 10/31/81	113,045	113,045
215	Centro De Estudos De Reproducao Humana de Botucatu Botucatu, Sao Paulo, Brazil	Renzo <u>Antonini</u> Filho, M.D.	"Chemical Sterilization in the Cebus Appella Monkeys"	5/15/80- 12/31/81	16,775	16,674.90
216(P19)	University of New Mexico Albuquerque, New Mexico	John C. Slocumb, M.D.	"Identification and Evaluation of Herbs Used by Native Healers to Affect Fertility"	5/1/80- 8/31/81	36,734	36,734
217(111N)	The University of Texas Health Science Center at San Antonio San Antonio, Texas	Carlton A. Eddy, Ph.D. Len Laufe, M.D. (IFRP)	"An Evaluation of the Efficacy of Fimbrial Enclosure With Silastic Devices as a Reversible Female Sterilization Technique"	7/1/80- 5/31/82 IFRP	56,252 4,534.88 (IFRP)	 4,534.88
218	Jefferson Medical College of Thomas Jefferson University Philadelphia, Pennsylvania	Leonard J. Lerner, Ph.D.	"Development and Mechanism of Activity Studies With the Pregnancy Terminating Compounds DL-111-IT and DL-105-IT"	7/1/80- 9/30/81	67,807	67,807

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219	Southern Research Institute Birmingham, Alabama	Richard L. Dunn, Ph.D.	"A Fibrous Polymer for Delivery of Quinacrine to the Human Reproductive Tract -- Related to PARFR-P57"	9/1/80-12/31/81	\$ 47,999	\$ 47,999
220	-----Joseph E. Davis, M.D.----- New York, New York		"New Method for Obstructing the Vas Deferens by Direct Injection of Chemical Agents: A Non-Operative Technique of Male Sterilization"	9/1/80-12/31/81	13,721	11,521
221C	Medical Dynamics, Inc. Englewood, Colorado	Edwin L. Adair, M.D.	"A Multi-Site Evaluation in Developed and Developing Countries of a Technique and Equipment for Transcutaneous Closure of the Vas Deferens by Electro Coagulation"	9/1/80-8/31/81	15,960	5,363.70
221Ba	Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil	Jose Freitas-Melo, M.D.	(SAME AS ABOVE)	9/15/80-9/14/81	13,970	2,953.50
221Bb	PROPATER Sao Paulo, Brasil	Marcos Paulo P. de Castro, M.D.	(SAME AS ABOVE)	9/15/80-9/14/81	14,245	10,017.70
222(107N)	Medical Research Foundation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Is Sperm Antigen a Causative Agent for Atherosclerosis After Vasectomy"	7/1/80-12/31/80	17,601	17,597.53
223	Southwest Foundation for Research and Education San Antonio, Texas	Joseph W. Goldzieher, M.D.	"Antigestational Effects of LHRH Analogues"	9/1/80-11/30/81	35,948	35,712.88

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224	Washington University St. Louis, Missouri	Arpad I. Csapo, M.D.	"Luteolysis in the Guinea Pig"	10/1/80- 3/31/81	\$34,959	\$ 18,081.36
225	Southern Research Institute, Birmingham, Alabama	Danny H. Lewis, Ph.D.	"Preparation of Nore- thisterone Microcapsules"	11/1/80- 8/31/81	34,217	34,217
225B	Maternidade Climerio de Oliveira Bahia, Brasil	Elsimar Metzker Coutinho, M.D.	"Clinical Trials of the Norethisterone Microcap- sule Injectable Contra- ceptive System"	4/1/81- 6/30/82	39,226	28,209.38
225M	Instituto de Investi- gacion Cientifica, Durango, Mexico	Roberto Rivera, M.D.	"Preparation of Nore- thisterone Microcapsules"	2/1/81- 12/31/81	4,693	4,692.60
225Ma	Instituto de Investi- gacion Cientifica Durango, Mexico	Roberto Rivera, M.D.	"Clinical Trials of the Norethisterone Micro- capsule Injectable Con- traceptive System"	4/1/81 6/30/82	41,063	40,298.50
225UAB	University of Alabama in Birmingham Birmingham, Alabama	Charles E. Flowers, Jr., M.D.	"Clinical Trials of the Norethisterone Injectable Contraceptive System"	4/1/81- 3/31/82	12,825	
226B	Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil	Elsimar Metzker Coutinho, M.D.	"Clinical Trial of Fallopian Tube Closure Using MCA"	9/15/80- 6/30/82	41,305	41,304.45
226C	Instituto de Obstetricia y Ginecologia, Facultad de Medicina, Universidad Austral de Chile Valdivia, Chile	Rene Guzman-Serani, M.D.	"Clinical Trials of Fallopian Tubal Closure Using MCA"	4/1/81- 6/30/82	24,145	24,145

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227B	Maternidade Climerio de Oliveira, Salvador, Bahia, Brasil	Hugo Maia, M.D.	"Prostaglandin Levels in the Human Follicular Fluid in Relation to the Moment of Ovulation"	3/1/81-11/30/81	13,613	\$ 13,612.50
228	University of California-San Diego, La Jolla, California	Samuel S.C. Yen, M.D.	"Induction of Luteolysis and Ovulation Inhibition by LRF-Analogues"	4/1/81-3/31/82	34,977	34,977
229	The Cornell University Medical College, New York, New York	B. Saxena, Ph.D., D.Sc. Gopi N. Gupta, Ph.D. William Ledger, M.D.	"A Clinical Evaluation of the Subdermal Contraceptive Norethindrone Pellet"	1/1/81-12/31/81	77,813	77,813
229B	Maternidade Climerio de Oliveira Bahia, Brasil	Elsimar Metzker Coutinho, M.D.	"Studies on Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implants"	3/1/81-6/30/82	32,461	
229M	Instituto de Investigacion Cientifica Durango, Mexico	Roberto Rivera, M.D.	"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant"	3/1/81-6/30/82	36,843	35,692.27
230	H.F.D. Design Crystal Lake, Illinois	N/A	"Design and Manufacture of 1500-2000 Wing Sound II Devices"	1/1/81-12/15/81	33,000	33,000
232	Northwestern University Evanston, Illinois	Erwin Goldberg, Ph.D.	"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase-C ₄ "	3/1/81-3/15/82	60,018	
233	Southwest Foundation for Research and Education San Antonio, Texas	Joseph W. Goldzieher, M.D. Daniel Castracane, Ph.D.	"Potentially Antifertility Activity of LH/HCG Peptide Fragments"	4/15/81-5/14/82	44,090	44,086.54

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235SRI	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the Female Reproductive Tract - Continuation of PARFR-206SRI"	4/1/81- 12/31/81	\$ 24,487	\$ 24,464.57
235UAB	University of Alabama in Birmingham Birmingham, Alabama	Lee R. Beck, Ph.D.	"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the Female Reproductive Tract - Continuation of PARFR-206UAB"	4/1/81- 6/30/82	29,789	
236IIT	IIT Research Institute Chicago, Illinois	Rejendra G. Mehta, Ph.D.	"Retinoids and Male Contraception"	6/1/81- 6/30/82	61,908	
237	Medical Research Foundation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Detection of Pregnancy in Women Before Implantation"	6/1/81- 2/28/82	9,391	9,314.27
238C	Universidad Austral de Chile Valdivia, Chile	Rene Guzman-Serani, M.D.	"Radio-Opaque MCA - Cineflourography Study"	6/15/81- 12/14/81	6,985	6,975
239	Center for the Advancement of Reproductive Health, Inc. Chapel Hill, North Carolina	Gary S. Berger, M.D.	"Clinical Trial of the Collagen Sponge As A Contraceptive"	6/1/81- 5/31/82	31,890	12,944.40
240	Presbyterian Hospital, Obstetrical and Gynecological Service, New York, New York	Ralph M. Richart, M.D. Robert S. Neuwirth, M.D.	"Data Collection and Analysis of MCA/FEMCEPT Clinical Trials (Previously PARFR-200C)"	7/1/81- 6/30/82	24,440	

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241	PIACT Seattle, Washington	Michael J. Free, Ph.D.	"Measurements of Electrical Characteristics of Equipment for Transcutaneous Electrocoagulation of the Vas Deferens"	7/20/81- 8/31/81	\$ 8,243.44	\$ 6,816.45

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 7/1/80 - 6/30/82

PARFR #	INSTITUTION	PRINCIPAL INVESTIGATOR	TITLE	DATES	BUDGET	TOTAL EXPENDITURES WHEN TERMINATED
P50	The University of Arizona Tucson, Arizona	Milos Chvapil, M.D. Ph.D.	"Effect of Spermicidal Detergent, Nonoxynol-9 on Liver Function"	7/1/79- 6/30/80	\$ 8,000	\$ 2,078.37
P51	----- Harrith M. Hasson, M.D. ----- Chicago, Illinois		"Graphic Assessment of Uterine Shape"	10/1/79- 9/30/80	10,000	10,000.00
P52	Corporacion Centro Regional de Poblacion, Bogota, Colombia	Jose Perea-Sasiain, M.D.	"Effects of Gossypol on Pregnancy"	10/1/79- 9/30/80	7,000	4,548.80
P53	The University of Texas Health Science Center at San Antonio, Texas	Ricardo H. Asch, M.D.	"Antifertility Effects of Luteinizing Hormone Releasing Hormone Ana- logue in the Female Rhesus Monkey"	11/1/79- 10/31/80	7,500	7,485.77
P54	Centro de Reproducao Humana - Sao Paulo, Brasil	Marcos Paulo P. de Castro, M.D.	"Percutaneous Injection of Monoethanolamine Oxide as a Vas Deferens Sclerosing Agent"	1/1/80- 6/30/80	9,350	4,529.00
P55	Duke University Durham, North Carolina	Vladimir Petrow, Ph.D.	"1-Hydroxyestra-1,3,5(10)- TRIEN-17B-OLS and Con- geners as Contragestative Agents"	11/1/79- 6/30/81	7,590	7,495.91
P56	Medical Research Foun- dation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Efficacy Testing of Frisch Intra-vascular Implants"	11/1/79- 10/31/80	14,665	13,360.90
P57	Southern Research Institute Birmingham, Alabama	Richard L. Dunn, Ph.D.	"A Fibrous Polymer for the Delivery of Quina- crine to the Human Reproductive Tract"	1/1/80- 6/30/80	7,428	7,401.43

PARFR/NORTHWESTERN UNIVERSITY
 PILOT STUDIES: AID/DSPE-C-0035
7/1/80 - 6/30/82

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
P58	Northwestern University Evanston, Illinois	Erwin Goldberg, Ph.D.	"Immunologic Suppression of Fertility by a Synthetic Antigenic Determinant of Lactate Dehydrogenase-C4"	12/1/79- 2/28/81	\$ 7,500	\$7,500.00
P59	University of Alabama in Birmingham Birmingham, Alabama	Richard E. Blackwell, Ph.D.	"The Development and Clinical Testing of an Estrogen Bromocryptine Regime as an Interceptive and/or Abortifacient Means of Fertility Regulation"	5/1/80- 10/31/80	7,500	7,500.00
P60	Michael Reese Hospital and Medical Center Chicago, Illinois	Antonio Scommegna, M.D.	"Prostaglandin Antagonists as Local Antifertility Agents"	8/1/80- 1/31/81	6,850	6,850.00
P61	Northwestern University Evanston, Illinois	Erwin Goldberg, Ph.D.	"Immunologic Suppression of Fertility <u>In Vitro</u> by Antisera to a Synthetic Antigenic Determinant of Lactate Dehydrogenase-C4"	8/1/80- 7/31/81	7,500	7,500.00
P62	University of Arizona Tucson, Arizona	Milos Chvapil, M.D., Ph.D. William Droegemuller, M.D.	"Testing a New Polymer Sheet Hypan™, to be Used As a Hood for Modified Aldrich Reversible Sterilization Method"	3/1/81- 9/30/81	7,479	7,478.86
P63	Michael Reese Hospital and Medical Center Chicago, Illinois	Antonio Scommegna, M.D.	"Prostaglandin Antagonists as Local Antifertility Agents"	6/15/81- 12/14/81	7,504.53	7,142.00

NORTHWESTERN UNIVERSITY

DIRECT PAYMENTS RELATED TO PARFR APPROVED SUBCONTRACTS
 Account: 4263-404-90 (92) -- Contract: AID/DSPE-C-0035

PARFR #	PAYEE	RELATES TO	BUDGET	AMOUNT PAID
D-1	INTERNATIONAL FERTILITY RESEARCH PROGRAM Research Triangle Park, North Carolina Req. #9197	IFRP manufacture of Tubal Hoods for PARFR-217(111N).	\$4,534.88	\$4,534.88
D-2	THE CORNELL UNIVERSITY MEDICAL COLLEGE New York, New York Req. #9937	Purchase of Gupta/Saxena NET pellets for PARFR-229B (Brasil) and 229M (Mexico) and plungers.	630	630
D-3	THE OHIO STATE UNIVERSITY DEVELOPMENT FUND Columbus, Ohio c/o Vernon C. Stevens, Ph.D. Req. #9943	PARFR-89N (Gregor) - baboon study.	4,940	4,940
D-4	UNIVERSITY OF ALABAMA IN BIRMINGHAM c/o Lee R. Beck, Ph.D. Req. #5445	UAB preparation of IND application for PARFR-214(83N).	1,175.21	1,175.21
D-5	ASOCIACION DEMOGRAFICA SALVADORENA San Salvador, El Salvador c/o Gustavo Argueta, M.D. Req. #5446, #2452	Follow-up of MCA/FEMCEPT patients enrolled in PARFR-86Sa.	2,880	1,900
D-6	COLUMBIA UNIVERSITY New York, New York c/o Harry P. Gregor, Ph.D. Req. #5447	Overrun on Gregor Silver Acetate/ Alginate project - PARFR-89N	1,345.95	1,345.95
D-7	UNIVERSITY OF ALABAMA IN BIRMINGHAM c/o Lee R. Beck, Ph.D. Req. #9313	Maintenance of 10 baboons from 10/31/80- 3/31/81 (151 days @ \$28.30/day) to bridge the gap between PARFR-206UAB and PARFR-235UAB.	4,273.30	4,273.30

NORTHWESTERN UNIVERSITY

DIRECT PAYMENTS RELATED TO PARFR APPROVED SUBCONTRACTS
 Account: 4263-404-90 (92) -- Contract: AID/DSPE-C-0035

<u>PARFR #</u>	<u>PAYEE</u>	<u>RELATES TO</u>	<u>BUDGET</u>	<u>AMOUNT PAID</u>
D-8	UNIVERSITY OF CHICAGO Central Shop-Physical Sciences Division Chicago, Illinois c/o Raymond Byrnes Req. #9373	Purchase of 2 UTD carrier instruments for PARFR-207.	\$8,000	
D-9	EDER INSTRUMENT COMPANY Chicago, Illinois Req. #9374	Manufacture and purchase of a steerable hysteroscope for Dr. Hosseinian (PARFR-207).	8,025	
D-10	CORNELL UNIVERSITY MEDICAL COLLEGE New York, New York c/o Brij B. Saxena, Ph.D. Req. #9377	Purchase of Gupta/Saxena NET pellets and 8 trocars for PARFR-301C (Chile) and PARFR-301T (USA).	2,415	2,415
D-11	RODOLFO QUINONES, M.D. Mexico City, Mexico Req. #1814	Screening of 15 patients for study that never started due to delays in equipment manufacture (PARFR-307M - Not Executed).	495	495
D-12	BECKMAN INSTRUMENTS Palo Alto, California Req. #9944	Synthesis and purchase of McKern's peptide for PARFR-233.	9,500	9,500
D-13	PIACT (Program for the Introduction of Contraceptive Technology) Seattle, Washington Req. #2451	Tests performed under subcontract PARFR-241		911.06

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
 July 1, 1975 - June 30, 1980
 56 Subcontracts (19 of which were extensions from Minnesota)

PARFR #	INSTITUTION	PRINCIPAL INVESTIGATOR	TITLE	DATES	BUDGET	TOTAL EXPENDITURES WHEN TERMINATED
51N	Johns Hopkins University Baltimore, Maryland	Donald S. Coffey, Ph.D.	"A New and Rapid Method for Obstructing the Vas Deferens by Direct Injec- tion of Chemical Agents"	7/1/75- 3/24/76	\$ 44,058	\$ 26,493.62
54N	Planned Parenthood-Buffalo Jamaica Family Planning Association, Ltd. St. Ann's Bay, Jamaica	Jack Lippes, M.D. Lenworth Jacobs, M.D.	"An Evaluation of Loops C and D with Copper Compar- ing Results in a Developed and a Developing Country"	7/1/75- 12/31/77	50,247	47,566.67
60N	University of Illinois Chicago, Illinois	Jerzy Jozef Bienzenski, M.D.	"Fertility Control by Thyrotropin Releasing Hormone"	7/1/75 9/30/75	2,800	2,806.50
63N	University of Chicago Chicago, Illinois	A.H. Hosseinian, M.D.	"Development of a Rever- sible and Permanent Uterotubal Blocking Technique by Hysteroscopy"	7/1/75- 9/30/75	17,383	17,382.79
63B	University of Illinois Chicago, Illinois	Lourens J.D. Zaneveld D.V.M., Ph.D.	"Baboon Studies for PARFR-63N"	10/1/75- 6/30/79	35,938	35,926.19
-----Additional costs related to 63N, 63B-----			Sollie Lucero -----			\$ 3,114.92
			Univ. of Chicago-Central Shop -----			5,877.85
			Zaneveld (Consultant) -----			1,200.00
65N	Boston University Boston, Massachusetts	Herbert H. Wotiz, Ph.D.	"Synthesis, Biochemistry and Biological Testing of End-Organ Specific Anti-Fertility Agents"	7/1/75- 12/31/76	78,346	77,705.06
66N	Columbia University New York, New York	Ralph M. Richart, M.D.	"Collaborative Study on Hysteroscopic Sterili- zation Procedures"	7/1/75- 8/31/75	2,730	2,390.40

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
 July 1, 1975 - June 30, 1980

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
67N	Oklahoma State University Stillwater, Oklahoma	Richard J. Orts, Ph.D.	"Effects of a Pineal Antigonadotropin on Ovulation, Implantation and Pregnancy"	7/1/75- 6/30/77	\$ 80,300	\$ 80,267.77
68N	Medical College of Georgia Augusta, Georgia	R.B. Greenblatt, M.D.	"The Potential Role of Crystalline Estradiol Implants for Sustained Ovarian Inhibition in Humans"	7/1/75- 10/31/76	41,953	40,489.20
69N	Michael Reese Medical Center Chicago, Illinois	Antonio Scommegna, M.D.	"Contraceptive Action of 6-Dehydroretroprogesterone Delivered to the Uterine Cavity via a Silastic T"	7/1/75- 9/30/76	53,263	53,082.64
70N	Medical Research Foundation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Vasectomy: Role of Antibodies"	7/1/75- 6/30/77	93,460	93,028.38
71N	University of California San Francisco, California	Pentti Siiteri, Ph.D.	"Inhibitors of Estrogen Biosynthesis in Fertility Regulation"	7/1/75- 3/31/76	15,061	15,053.99
73N	Battelle Columbus Laboratories Columbus, Ohio	Richard D. Falb, Ph.D.	"Development of a Temperature Sensing Electrocautery Probe for Transcervical Sterilization"	7/1/75- 6/30/76	17,161	17,161.00
74N	University of Minnesota Minneapolis, Minnesota	Kailash Kedia, M.D.	"Pharmacological Male Contraception"	7/1/75- 12/31/75	29,044	21,178.04
75N	Medical College of Georgia Augusta, Georgia	Edwin Bransone, M.D. Virendra Mahesh, D.Sc., Ph.D.	"Testing the Anti-Fertility Effects of Equilenin and Derivatives <u>In Vivo</u> "	7/1/75- 3/1/76	39,252	39,252.00

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
76N	University of Alabama Birmingham, Alabama	Lee R. Beck, Ph.D.	"Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone"	7/1/75- 9/30/75	\$ 11,729	\$ 9,337.94
77N	University of Hawaii Honolulu, Hawaii	Milton Diamond, Ph.D.	"Development of an Intra-Uterine Sterilizing Device"	7/1/75- 1/31/76	9,279	9,275.64
78N	Abcor, Inc. Cambridge, Massachusetts	Elie S. Nuwayser, Ph.D.	"Development of an Injectable Polymer System for Tubal Occlusion"	7/1/75- 2/29/76	33,287.10	33,287.10
79N	University of Vermont Burlington, Vermont Maine Medical Center Portland, Maine	C. Irving Meeker, M.D.	"A Method for Reversible Sterilization in the Female"	2/1/77- 8/31/77 9/1/77- 6/30/80	81,090 106,131	32,369.51 104,924.21
80N	Washington University St. Louis, Missouri	David W. Keller, M.D.	"Fertility Control Through Local Cervical Injection of Microencapsulated Progestins"	7/1/75- 7/11/78	168,526	159,380.31
81N	University Hospitals Essen, Germany	Peter F. Tauber, M.D.	"Clinical Evaluation of Intrauterine Devices Containing Epsilon Aminocaproic Acid (EACA)"	5/1/76- 9/30/78	62,595	60,297.23
82N	Al-Azhar University Cairo, Egypt	Fouad Hefnawi, M.B., M.S.	"Measurement of Blood Loss of Women Fitted With Copper-Clad Lippes Loops"	11/1/75- 4/30/79	74,300	71,120.79

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
83N	University of Alabama Birmingham, Alabama	Lee R. Beck, Ph.D.	"Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone"	4/1/76- 3/31/80	\$257,849	\$257,848.66
84N	Planned Parenthood of Buffalo, Inc.	Jack Lippes, M.D.	"Evaluation of the Copper-T IUD as a Post-Coital Method of Contraception"	10/1/77- 8/15/78	2,600	2,568.63
85N	The University of Arizona Tucson, Arizona	Milos Chvapil, M.D., Ph.D.	"Development of Collagen Sponge Containing Spermicide"	12/1/76- 6/30/80	98,124	97,895.49
86N	The St. Luke's Institute for Health Sciences New York, New York	Robert S. Neuwirth, M.D. Ralph M. Richart, M.D.	"Phase I Clinical Trial of Fallopian Tube Closure Using Methylcyanoacrylate (MCA) Tissue Adhesive Delivered Through the Single-Application Fertility Regulation (FEMCEPT) Device"	6/1/78- 3/31/80	36,602	36,489.98
86G	Bureau Mengen Cologne, Germany	Prof. H.K. Zinser Evangelisches Krankenhaus	---(SAME TITLE AS 86N)---	9/1/78- 8/31/79	27,159	22,096.53
86K	Korea University College of Medicine Seoul, Korea	Sung-bong Hong, M.D.	---(SAME TITLE AS 86N)---	5/1/79- 4/30/80	16,080	9,140.41
86Sa	Asociacion Demografica Salvadorena San Salvador, El Salvador	Gustavo Argueta, M.D.	---(SAME TITLE AS 86N)---	3/15/79- 3/14/80	12,410	9,911.00
86Sb	Instituto Salvadorena del Seguro Social San Salvador, El Salvador	Ernesto Moran, M.D.	---(SAME TITLE AS 86N)---	3/15/79- 3/14/80	8,000	1,360.00
------(Dr. Moran Caceres left El Salvador - This subcontract will not receive a final invoice.)-----						

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
87N	Reza Pahlavi Medical Center Tehran, Iran	Abdol Hosseinian, M.D.	"Development of a Safe and Effective Hystero-scopic Sterilization Technique by Using Utero-tubal Blocking Devices"	11/1/76- 8/31/77	\$ 17,300	\$ 17,310.48
88N	Planned Parenthood Federation of America, Inc. New York, New York	Louise B. Tyrer, M.D.	"Study to Determine the Safety and Efficacy of Copper-Releasing IUDs as a Method of Post-Coital Contraception"	4/1/77- 8/31/78	83,020	44,162.00
89N	Columbia University New York, New York	Harry P. Gregor, Ph.D.	"Fallopian Tube Cauterization and Closure by Silver Acetate - Alginate Formulations"	1/15/77- 6/30/80	112,073	112,073.00
	-----St. Luke's Medical Center Agreement	(animal work)-----		11/1/77- 6/30/80	63,326	50,617.49
90N	New York Medical College Valhalla, New York	Joseph E. Davis, M.D.	"New Method for Obstructing the Vas Deferens by Direct Injection of Chemical Agents: A Non-Operative Technique of Male Sterilization"	6/1/77 12/31/78	59,305	39,772.26
90Np	Planned Parenthood Federation of America, Inc. New York, New York	Joseph E. Davis, M.D.	---(SAME TITLE AS 90N)---	2/1/79- 6/30/80	54,007	52,215.03
91N	Dynatech R/D Company Cambridge, Massachusetts	Donald L. Wise, Ph.D.	"Preparation and Evaluation of Biodegradable Cylindrical Implants for Fertility Control"	6/1/77- 6/30/80	177,141	175,116.33

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
92N	Medical Research Foundation of Oregon Portland, Oregon	Deborah J. Anderson, Ph.D.	"Contraception by Induction of Mild Uterine Inflammation"	6/1/77- 12/31/79	\$ 86,108	\$ 85,524.48
93N	National Academy of Sciences Washington, D.C.	Nancy Muckenhirn, Ph.D.	"Workshop on Animal Models For Research on Fertility and Contraception"	8/1/77- 6/30/79	50,500	50,362.22
94N	University of Arizona Tucson, Arizona	William Droegemueller, M.D.	"Modern Modified Aldridge Procedure"	12/1/77- 12/31/79	62,062	44,715.58
	-----University of Illinois Agreement (Animal Work)-----			10/1/78- 12/31/79	17,850	14,960.75
95N	University of Illinois Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D.	"Development and Evaluation of a Reversible Vas Deferens Blocking Device"	7/1/77- 9/30/79	113,348	113,348.00
96N	PROJECT NEVER STARTED -----					
97N	The Johns Hopkins University Baltimore, Maryland	Theodore M. King, M.D., Ph.D.	"Research on Instillation Techniques for Pregnancy Termination in Korea"	8/1/78- 6/30/80	108,442	46,528.38
97K	Yonsei University College of Medicine Seoul, Korea	Hyun-Mo Kwak, M.D.	---(SAME TITLE AS 97N)---	7/1/78- 6/30/80	66,550	37,066.39
98M	Centro de Investigacion Sobre Fertilidad y Esterilidad (CIFE) Mexico City, Mexico	Ramon Aznar, M.D.	"Norethisterone Microcapsule Injectable Contraceptive Study"	7/1/78- 6/30/80	34,265	33,076.12
	-----UAB Agreement-----			7/1/78- 6/30/80	10,780	10,779.63
	-----SRI Agreement-----			7/1/78- 6/30/79	27,642	27,642.00

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
 July 1, 1975 - June 30, 1980

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
99N	Oklahoma State University Stillwater, Oklahoma	Duane Garner, Ph.D.	"Immunoabsorbent Isolation of Specific Spermatozoal Antigens for Use as Anti-Fertility Immunogens"	7/1/78- 3/31/79	\$ 30,233	\$ 25,752.43
100N	Jefferson Medical College of The Thomas Jefferson University Philadelphia, Pennsylvania	Leonard J. Lerner, Ph.D.	"Investigation of New Compounds to Terminate Pregnancy"	9/1/78- 6/30/80	109,384	109,384.00
101N	Southwest Foundation for Research and Education San Antonio, Texas	Joseph W. Goldzieher, M.D.	"Metabolism and Pharmacokinetics of Ethynyl Estrogens"	9/1/78- 2/28/79	23,994	23,958.65
102N (P10)	University of Illinois Chicago, Illinois	Robert T. Chatterton, Ph.D.	"Fertility Regulation by Control of Progesterone Clearance"	11/1/78- 10/31/79	46,767	40,126.85
103N	IIT Research Institute Chicago, Illinois	Allan P. Gray, Ph.D.	"Microencapsulation of Progesterone Antibodies"	11/1/78- 10/31/79	28,108	28,108.00
-----Companion Project to PARFR-102N(P10)-----						
104N (P9)	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the Female Reproductive Tract"	11/1/78- 10/31/79	66,000	66,000.00
105N	Centro de Investigacion Sobre Fertilidad y Esterilidad (CIFE) Mexico City, Mexico	Harry Rudel, M.D.	"A Study of a Parenterally Administered Progesterone-Cholesterol Formulation for Use as a Post-Partum Injectable Contraceptive"	5/1/79- 4/30/80	56,236	26,924.23

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
 July 1, 1975 - June 30, 1980

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
106N	University of North Carolina Chapel Hill, North Carolina	Gary S. Berger, M.D.	"Effects of Tubal Sterilization on Menstruation: A Prospective Controlled Study"	2/1/79- 2/29/80	\$ 47,676	\$ 47,672.38
107N	Medical Research Foundation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Is Sperm Antigen a Causative Agent for Atherosclerosis After Vasectomy"	4/1/79- 6/30/80	83,318	78,806.18
108N	Planned Parenthood Federation of America, Inc. New York, New York	Louise B. Tyrer, M.D.	"Study to Determine the Safety, Acceptability and Effectiveness of the Female Contraceptive Barrier Intra-Vaginal Device (IVD)"	3/1/79- 7/11/79	62,600	4,717.73
109	NUMBER NOT ASSIGNED -----					
110N	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"Optimization of an Injectable Microcapsule Formulation for the 90-Day Delivery of Norethisterone"	4/1/79- 3/31/80	65,972	65,972.00
111N	The University of Texas Health Science Center at San Antonio San Antonio, Texas	Carlton A. Eddy, Ph.D.	"An Evaluation of the Efficacy of Fimbrial Enclosure With Silastic Devices as a Reversible Female Sterilization Technique"	6/1/79- 6/30/80	58,290	55,258.15
	-----IFRP Agreement -----				3,340	3,340.00
112	NUMBER NOT ASSIGNED -----					

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 PARFR SUBCONTRACTS SUPPORTED AT NORTHWESTERN UNIVERSITY
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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
113	NUMBER NOT ASSIGNED					
114N	University of California- San Diego La Jolla, California	Samuel S.C. Yen, M.D.	"The Induction of Luteo- lysis and Ovulation Inhibition by LRF-Agonist"	6/15/79- 6/30/80	\$ 65,959	\$ 61,557.42

----- PARFR-114N is the Last Subcontract Committed on AID/csd-3608 -----

7/31/81

PARFR/Northwestern University Executed Pilot Studies: AID/csd-3608

November 1, 1975 - June 30, 1980

21 Subcontracts (2 never started)

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
P1	University of Nebraska Omaha, Nebraska	James E. McClurg, Ph.D.	"Secretory Immune Response of the Female Genital Tract"	11/1/75- 1/15/77	\$ 6,000	\$6,000
P2	University of Arizona Tucson, Arizona	Milos Chvapil, M.D. Ph.D.	"Zinc-Collagen Sponge Com- plex as a Contraceptive, Section I - Lab Studies"	1/31/76- 3/31/76	6,000	5,322.44
P3	University of Arizona Tucson, Arizona	Milos Chvapil, M.D. Ph.D.	"Zinc-Collagen Sponge Com- plex as a Contraceptive, Section II - Clinic Studies"	2/1/76- 4/30/76	6,000	5,006.50
P4	Harbor General Hospital Torrance, California	A.F. Parlow, Ph.D.	"Active Immunization of the Human Follicle Stimu- lating Hormone to Inhibit Gonadal Function"	1/1/77- 12/31/77	6,000	- 0 -
P5	University of Minnesota Minneapolis, Minnesota	Bo G. Crabo, Ph.D.	"Contraceptive Effect of Low Oral Doses of 2,6-cis- Diphenylhexanethylcyclote- trasiloxane in the Male"	9/1/76- 8/31/77	5,850	5,850
P6	University of Illinois at the Medical Center Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D.	"Development and Evalua- tion of a Reversible Vas Deferens Blocking Device"	9/1/76- 8/31/77	5,985	5,985
P7	NEVER EXECUTED -----					
P8	The Emko Company St. Louis, Missouri	Charles Salivar Ray Belsky	"Water Soluble Condom Feasibility Study"	9/15/77- 6/15/78	5,789.78	5,468.07

PARFR/Northwestern University Executed Pilot Studies: AID/csd-3608

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<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
P9	Southern Research Institute Birmingham, Alabama	Danny H. Lewis, Ph.D.	"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the Female Reproductive Tract"	1/1/78- 6/30/78	\$ 6,000	\$6,000.00
P10	University of Illinois Chicago, Illinois	Robert T. Chatterton, Ph.D.	"Fertility Regulation by Control of Progesterone Clearance"	1/1/78- 10/31/78	7,216.78	6,048.62
P11	Columbia University New York, New York	Ralph M. Richart, M.D.	"Evaluation of Carbohexo- xymethyl-2-Cyanoacrylate as a Tube Blocking Agent"	2/1/78- 3/31/79	7,004.01	7,004.03
P12	Massachusetts Institute of Technology Cambridge, Massachusetts	David Frisch, Ph.D.	"Development of Micro- porous Materials for Thin Intravasal Implants"	7/1/78- 6/30/80	15,000	14,035.55
P13	Catholic University of Leuven, Leuven, Belgium	Ivo Brosens, M.D., Ph.D. Len Laufe, M.D. (IFRP)	"An Evaluation of the Efficacy of Candidate Fimbrial Prosthesis in Female Rabbits and the Evaluation of Fimbrial Devices as a Reversible Technique of Female Sterilization"	5/1/78- 4/30/80	11,680.59 (Belgium) 2,750.00 (IFRP)	11,377.53 2,750.00 (IFRP)
P14	-----Stanwood Schmidt, M.D.----- Eureka, California		"The Bipolar Needle for Percutaneous Vas Obstruction"	7/1/78- 6/30/79	2,350	- 0 -
P15	New York Medical College Valhalla, New York	Sidney Shulman, Ph.D.	"Isolation of Effective Sperm Antigen for Use in Contraceptive Immuniza- tion"	3/1/79- 2/29/80	7,500	7,500.00

PARFR/Northwestern University Executed Pilot Studies: AID/csd-3608

November 1, 1975 - June 30, 1980

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
P16	University of California San Francisco, California	Ernest W. Page, M.D.	"Investigations of a New Vaginal Barrier Contraceptive"	1/1/79- 6/30/80	\$ 6,000	\$2,750.11
P17	Southern Illinois University Carbondale, Illinois	Matthew Freund, Ph.D.	"Development and Testing of a New Intravaginal Contraceptive Method and Device (IVCD)"	2/1/79- 9/30/79	7,500	6,791.60
P18	University of Georgia Athens, Georgia	Marion M. Bradford, Ph.D.	"Evaluation of Acrosin-Acrolysin Inhibitors as Male Contraceptive Agents"	2/1/79- 10/31/79	7,500	7,499.73
P19	University of New Mexico Albuquerque, New Mexico	John C. Slocumb, M.D.	"Identification and Evaluation of Herbs Used by Native Healers to Affect Fertility"	2/1/79- 6/30/80	7,700	7,693.96
P20	Southwest Foundation for Research and Education San Antonio, Texas	Joseph Goldzieher, M.D.	"Effect of the Estrogen-Bromocryptine Regimen in the Post-Implantation Phase in Baboons"	6/1/79 11/30/79	7,500	7,461.45
P21	University of Arizona Tucson, Arizona	Milos Chvapil, M.D. Ph.D.	"Development and Preliminary Human Testing of the Retention of a New Intra-cervical Device (ICD)"	6/15/79- 6/14/80	7,500	5,151.06
P22	University of Houston Houston, Texas	Lindley A. Cates, Ph.D.	"A Preliminary Investigation of Fertility Regulation by South American Tribes"	6/15/79- 6/14/80	7,688	- 0 -

8/31/80

AID/csd-3808
 PARFR SUBCONTRACTS SUPPORTED AT MINNESOTA: 30 Subcontracts(29 projects)
 October 1, 1972 - June 30, 1975
 PARFR-50 to PARFR-80 (inclusive) excluding PARFR-79

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
50	University of Minnesota Minneapolis, Minnesota Jichi University, Japan	Takashi Okagaki, M.D., Ph.D. Taro Tamada, M.D.	"Acceptability and Use- Effectiveness of Condoms"	10/1/72- 5/30/75	\$80,000	\$83,755.28
51	Johns Hopkins University Baltimore, Maryland	Donald S. Coffey, Ph.D.	"A New and Rapid Method for Obstructing the Vas Deferens by Direct Injec- tion of Chemical Agents"	6/1/73- 5/31/75	67,521	67,182.77
52	Washington State Univ. Pullman, Washington	William M. Dickson, Ph.D.	"The Effect of Certain Indonesian Herbs on Early Pregnancy"	5/1/73- 4/10/74	1,841	1,642.93
53	University of Minnesota Minneapolis, Minnesota	Edmund F. Graham, Ph.D.	"The Use of Physiologic- ally Non-Toxic Organo- siloxane and Fluoro- chemical Liquids as Intravaginal Spermatozoan Trapping Mechanisms"	5/15/73- 6/30/75	75,110	75,858.95
54	Planned Parenthood, Buffalo Jamaica Family Planning Association, Ltd. St. Ann's Bay, Jamaica	Jack Lippes, M.D. Lenworth Jacobs, M.D.	"An Evaluation of Loops C and D with Copper Com- paring Results in a Developed and a Developing Country"	2/1/74- 6/30/75	28,668	10,602.49 (Buffalo) 8,464.00 (Jamaica)
55	University of California San Francisco, California	Alan Margolis, M.D.	"Clinical Evaluation of a Long-Term Intrauterine Drug Delivery System Based on Fluid-Filled IUD"	3/1/74- 6/30/75	51,992	11,296.37
56	University of Texas - San Antonio San Antonio, Texas	Carl J. Pauerstein, M.D.	"Pharmacologic Accelera- tion of Ovum Transport as a Contraceptive Method"	9/1/73- 6/30/75	96,589	96,578.27

AID/csd-3608
 PARFR SUBCONTRACTS SUPPORTED AT MINNESOTA: 30 Subcontracts(29 projects)
 October 1, 1972 - June 30, 1975

PARFR #	INSTITUTION	PRINCIPAL INVESTIGATOR	TITLE	DATES	BUDGET	TOTAL
						EXPENDITURES WHEN TERMINATED
57	University of Chicago Chicago, Illinois	Joseph Swartwout, M.D.	"Development of a Reversible Male Contraceptive Technique"	9/1/73- 2/28/75	\$64,772.44	\$52,259.68
58	University of Chicago Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D. (Transferred to IIT 7/1/74) Refer to PARFR-72	"Improving Effectiveness of Vaginal Contraceptive Creams or Jellies by Addition of Sperm Enzyme Inhibitors"	8/1/73 6/30/74 ---(Continued Under PARFR-72)---	83,782	33,300.43
59	New York Medical College Valhalla, New York	Delphine Bartosik, M.D.	"Bio-assay of Luteolytic Agents Using Human Corpora Lutea"	12/1/73- 12/31/74	28,671	26,033.17
60	University of Illinois Chicago, Illinois	Jerzy Jozef Bienzenski, M.D.	"Fertility Control by Thyrotropin Releasing Hormone"	3/15/74- 6/30/75	51,049	44,314.88
61	Michael Reese Hospital Chicago, Illinois	Paul Dimowski, M.D., Ph.D.	"Development of a Hysteroscopic Technic for Permanent Sterilization"	1/15/74- 6/30/75	70,085	44,856.06
62	Worcester Foundation for Experimental Biology, Inc. Shrewsbury, Massachusetts	R. H. Hooker, M.D.	"Reversible Suppression of Male Fertility by Implants Located at the Vas Deferens"	6/1/74- 6/30/75	41,020	41,642.83
63	University of Chicago Chicago, Illinois	A.H. Hosseinian, M.D.	"Development of a Reversible and Permanent Uterotubal Blocking Technique by Hysteroscopy"	4/1/74- 6/30/75	58,987	54,062.69

AID/csd-3608
 PARFR SUBCONTRACTS SUPPORTED AT MINNESOTA: 30 Subcontracts(29 projects)
 October 1, 1972 - June 30, 1975

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
64A	Oak Ridge Associated Universities Oak Ridge, Tennessee (In collaboration with the Southwest Foundation for Research and Education San Antonio, Texas)	Melvin M. Ketchel, Ph.D.	"Contraceptive Action of Diethylaminoethanol"	1/1/75-6/30/75	\$31,931	\$31,456.09
65	Boston University Boston, Massachusetts	Herbert Wotiz, Ph.D.	"Synthesis, Biochemistry and Biological Testing of End-Organ Specific Anti-Fertility Agents"	1/1/74-6/30/75	75,000	74,114.66
66	Columbia University New York, New York	Ralph M. Richart, M.D.	"Collaborative Study on Hysteroscopic Sterilization Procedures"	4/1/74-6/30/75	24,897	21,648.27
67	Oklahoma State University Stillwater, Oklahoma	Richard J. Orts, Ph.D.	"Effects of a Pineal Antigonadotropin on Ovulation, Implantation and Pregnancy"	4/1/74-6/1/75	34,329	34,556.78
68	Medical College of Georgia Augusta, Georgia	R.B. Greenblatt, M.D.	"The Potential Role of Crystalline Estradiol Implants for Sustained Ovarian Inhibition in Humans"	5/1/74-6/30/75	21,150	21,013.30
69	Michael Reese Medical Center Chicago, Illinois	Antonio Scommegna, M.D.	"Contraceptive Action of 6-Dehydroretroprogesterone Delivered to the Uterine Cavity Via a Silastic T"	5/1/74-6/30/75	46,751	17,460.90
70	Medical Research Foundation of Oregon Portland, Oregon	Nancy J. Alexander, Ph.D.	"Vasectomy: Role of Antibodies"	6/1/74-6/30/75	53,904	51,800.54

AID/csd-3608
 PARFR SUBCONTRACTS SUPPORTED AT MINNESOTA: 30 Subcontracts(29 projects)
 October 1, 1972 - June 30, 1975

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
71	University of California San Francisco, California	Pentti Siiteri, Ph.D.	"Inhibitors of Estrogen Biosynthesis in Fertility Regulation"	10/1/74- 6/30/75	\$36,326	\$36,278.05
72	IIT Research Institute Chicago, Illinois	Lourens J.D. Zaneveld, D.V.M., Ph.D.	[Zaneveld (PARFR-58) transferred from Univ. of Chicago to IIT Research] "Improving the Effectiveness of Vaginal Contraceptive Creams of Jellies by Addition of Sperm Enzyme Inhibitors"	7/1/74- 6/30/75	57,466	56,267.38
73	Battelle Columbus Laboratories Columbus, Ohio	Richard D. Falb, Ph.D.	"Development of a Temperature Sensing Electrocautery Probe for Transcervical Sterilization"	11/1/74- 6/30/75	34,257	26,478.18
74	University of Minnesota Minneapolis, Minnesota	Kailash Kedia, M.D.	"Pharmacological Male Contraception"	12/1/74- 6/30/75	33,265	17,000.00 (Approx.)
75	Medical College of Georgia Augusta, Georgia	Edwin Bransome, M.D. Virendra Mahesh, D.Sc., Ph.D.	"Testing the Anti-Fertility Effects of Equilenin and Derivatives <u>In Vivo</u> "	11/1/74- 6/30/75	35,368	32,680.35
76	University of Alabama Birmingham, Alabama	Lee R. Beck, Ph.D.	"Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone"	10/1/74- 6/30/75	31,308	33,502.28
77	University of Hawaii Honolulu, Hawaii	Milton Diamond, Ph.D.	"Development of an Intra-Uterine Sterilizing Device"	12/1/74- 6/30/75	20,068	10,789.76

AID/csd-3608
 PARFR SUBCONTRACTS SUPPORTED AT MINNESOTA: 30 Subcontracts(29 projects)
 October 1, 1972 - June 30, 1975

<u>PARFR #</u>	<u>INSTITUTION</u>	<u>PRINCIPAL INVESTIGATOR</u>	<u>TITLE</u>	<u>DATES</u>	<u>BUDGET</u>	<u>TOTAL EXPENDITURES WHEN TERMINATED</u>
78	Abcor, Inc. Cambridge, Massachusetts	Elie S. Nuwayser, Ph.D.	"Development of An Injectable Polymer System for Tubal Occlusion"	12/15/74- 6/30/75	\$21,459	\$19,776.21
80	Washington University St. Louis, Missouri	David W. Keller, M.D.	"Fertility Control Through Local Cervical Injection of Micro- encapsulated Progestins"	4/16/75- 6/30/75	13,474	12,479.38

LDC RESEARCH FUNDS

<u>PARFR #</u>	<u>Budget (Dollars)</u>	<u>Total Expenditures To Date</u>
<u>AID/csd-3608</u>		
PARFR-54 Jamaica	\$ 8,464	\$ 8,464.00 (Total)
PARFR-54N Jamaica	35,859	24,809.00 (Total)
PARFR-82N Egypt	74,300	71,120.79 (Total)
PARFR-86K Korea	16,080	9,140.41 (Total)
PARFR-86Sa El Salvador	12,410	9,911.00 (Total)
PARFR-86Sb El Salvador	8,000	1,360.00 (Total)
PARFR-87N Iran	17,300	17,310.48 (Total)
PARFR-97K Korea	66,550	37,066.39 (Total)
PARFR-98M Mexico	34,265	33,076.12 (Total)
PARFR-105N Mexico	56,236	26,924.23 (Total)
 <u>AID/DSPE-C-0035</u>		
PARFR-200K(86K) Korea	\$ 2,598	\$ 1,900.00
PARFR-200P Philippines	14,385	13,856.29
PARFR-201B Brasil	34,600	34,600.00 (Total)
PARFR-215 Brasil	16,775	16,674.90 (Total)
PARFR-221Ba Brasil	13,970	2,953.50 (Total)
PARFR-221Bb Brasil	14,245	10,017.70 (Total)
PARFR-225B Brasil	39,226	28,209.38 (Total)
PARFR-225M Mexico	4,693	4,692.60 (Total)
PARFR-225Ma Mexico	41,063	40,298.50 (Total)
PARFR-226B Brasil	41,305	41,304.45 (Total)
PARFR-226C Chile	24,145	24,145.00 (Total)
PARFR-227B Brasil	13,613	13,612.50 (Total)
PARFR-229B Brasil	32,461	29,538.30
PARFR-229M Mexico	36,843	35,692.27 (Total)
PARFR-236C Chile	6,985	6,975.00 (Total)
PARFR-P52 Colombia	7,000	4,548.80 (Total)
PARFR-P54 Brasil	9,350	4,529.00 (Total)
 <u>DPE-0546-A-00-1003-00</u>		
PARFR-301C Chile	\$31,476	\$ 7,834.20
PARFR-305V Venezuela	17,225	7,701.03
PARFR-310C Chile	8,000	3,652.00
PARFR-311C Chile	7,500	- 0 -
PARFR-314E Egypt	5,400	- 0 -
PARFR-316C Chile	24,000	- 0 -
PARFR-318B Brasil	14,982	- 0 -

PARFR SCIENTIFIC ADVISORY COMMITTEE

MEETING XXXVIII

Saturday, March 13, 1982

HYATT REGENCY O'HARE
at O'Hare International Airport
9300 W. Bryn Mawr Avenue
Rosemont, Illinois 60618
(312) 696-1234

AGENDA

CONTINENTAL BREAKFAST: 8:30 A.M., Consular Room (Near Pool)

CONVENE: 9:00 A.M., 3/13/82, Consular Room

I. ANNOUNCEMENTS

- A. Introduction of Dr. Dean Moyer as a SAC member for a 3-year term ending March, 1985.
- B. Dr. Scrimshaw's 3-year term ends with this meeting and we would like to thank her for her service and interest in PARFR.
- C. 1982 SAC Meetings: June 25, 1982 (Friday) Ambassador East, Chicago, Illinois
November, 1982, Date to be determined, Washington, D.C.

II. NEW BUSINESS

A. FORMAL PROPOSAL REVIEW

- * Prof. Tapani Luukkainen, M.D., Ph.D., University of Helsinki, Helsinki, Finland
"Development of Progestin-Releasing Intracervical Device and Studies on the Effectiveness of the Device"
- * John C.M. Tsibris, Ph.D., University of Illinois College of Medicine, Chicago, Illinois
"Guaiacol Peroxidase Levels in Cervical Mucus, Saliva and Vaginal Secretions: Possible Predictors of Ovulation"
- * David Heber, M.D., Ph.D., Harbor-UCLA Medical Center, Torrance, California
"Clinical Pharmacology of Gonadotropin by a Potent GnRH Antagonist in the Male and Female"

* REQUIRES ACTION

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B. EXTENSION PROPOSAL REVIEW

- * PARFR-205(95N) -- Lourens J.D. Zaneveld, D.V.M., Ph.D., University of Illinois at the Medical Center, Chicago, Illinois
"Development and Evaluation of a Reversible Vas Deferens Blocking Device, The Shug"
- * PARFR-232 -- Erwin Goldberg, Ph.D., Northwestern University, Evanston, Illinois
"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase C-4"
- * PARFR-229 -- Brij B. Saxena, Ph.D., D.Sc., Gopi N. Gupta, Ph.D. and William J. Ledger, Ph.D., The Cornell University Medical College, New York, New York
"Clinical Studies with the Bioabsorbable Contraceptive Norethindrone Pellets"

C. PILOT STUDY PROPOSAL REVIEW

- * Patricia B. Coulson, Ph.D., University of Tennessee, Knoxville, Tennessee
"The Comparative Effects of Gossypol on Adrenal and Testicular Steroidogenesis"

D. INFORMAL PROPOSAL REVIEW

- * James W. Simpkins, M.D., University of Florida, Gainesville, Florida
"Fertility Regulation Through Sustained Exposure to Narcotic Antagonists"
- * Manfred Philipp, Ph.D., Lehman College of the City University of New York
"Development of New Acrosin Inhibitors"

E. TECHNICAL REPORT REVIEW

- PARFR-207 -- Abdol H. Hosseinian, M.D., Chicago Medical School
"Hysteroscopic Sterilization by Using Uterotubal Blocking Devices"
- PARFR-211 -- Joseph E. Davis, M.D., New York, New York
"Study of Vas Occlusion in Animals Using Chemical Agents"
- PARFR-212(85N) -- Milos Chvapil, M.D., Ph.D. and William Droegemueller, M.D., The University of Arizona Health Sciences Center, Tucson, Arizona
"Development of Collagen Sponge Containing Spermicide and Post-Coital Testing of Collagen"

* REQUIRES ACTION

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E. TECNICAL REPORT REVIEW

PARFK-214(83N) [FINAL] -- Lee R. Beck, Ph.D., University of Alabama in Birmingham
"Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone"

PARFR-214(110N) [FINAL] -- Danny H. Lewis, Ph.D., Southern Research Institute, Birmingham, Alabama
"Optimization of an Injectable Microcapsule Formulation for the 90-Day Delivery of Norethisterone"

PARFR-215 (FINAL) -- Renzo Antonini, M.D., Universidade Estadual Paulista, Sao Paulo, Brasil
"Chemical Sterilization in the Cebus Appella Monkeys"

PARFR-217(111N) -- Carlton A. Eddy, Ph.D., The University of Texas Health Science Center at San Antonio
"An Evaluation of the Efficacy of Fimbrial Enclosure With Silastic Devices As a Reversible Female Sterilization Technique"

PARFR-218 (FINAL) -- Leonard J. Lerner, Ph.D., Jefferson Medical College of Thomas Jefferson University, Philadelphia, Pennsylvania
"Development and Mechanism of Activity Studies With the Pregnancy Terminating Compounds DL-111-IT and DL-105-IT"

PARFR-219 (FINAL) -- Richard L. Dunn, Ph.D., Southern Research Institute, Birmingham, Alabama
"A Fibrous Polymer for the Delivery of Quinacrine to the Human Reproductive Tract"

PARFR-220 (FINAL) -- Joseph E. Davis, M.D., New York, New York
"A New Method for Obstructing the Vas Deferens by Direct Injection of Chemical Agents: A Non-Operative Technique of Male Sterilization"

PARFR-223 (FINAL) -- Joseph W. Goldzieher, M.D., Southwest Foundation for Research and Education, San Antonio, Texas
"Antigestational Effects of LH-RH Analogues"

PARFR-229M -- Roberto Rivera, M.D., Instituto de Investigacion Cientifica, Juarez University of Durango, Mexico
"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive Norethindrone Pellet Implant"

PARFR-230 (FINAL) -- H.F.D. Design, Crystal Lake, Illinois
"Design and Manufacture of 1500 - 2000 Wing Sound II Devices"
(Dr. Hasson reports on pick up of Wing Sound II Devices and initiation of studies in Egypt and England.)

E. TECNICAL REPORT REVIEW (continued)

PARFR-235SRI (FINAL) -- Danny H. Lewis, Ph.D., Southern Research Institute,
Birmingham, Alabama

"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the
Female Reproductive Tract - Continuation of PARFR-206SRI"

PARFR-236IIT -- Rajendra G. Mehta, Ph.D., IIT Research Institute, Chicago,
Illinois

"Retinoids and Male Contraception"

PARFR-237 -- Nancy J. Alexander, Ph.D., Oregon Regional Primate Research
Center, Beaverton, Oregon

"Detection of Pregnancy in Women Before Implantation"

PARFR-239 -- Gary S. Berger, M.D., Center for the Advancement of Repro-
ductive Health, Inc., Chapel Hill, North Carolina

"Clinical Trial of the Collagen Sponge as a Contraceptive"

PARFR-241 (FINAL) -- Michael J. Free, Ph.D., PIACT, Seattle, Washington

"Measurements of Electrical Characteristics of Equipment for
Transcutaneous Electrocoagulation of the Vas Deferens"

PARFR-301T -- Ricardo H. Asch, M.D., The University of Texas Health Science
Center at San Antonio

"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive
Norethindrone Pellet Implant"

PARFR-302 -- Ricardo H. Asch, M.D., The University of Texas Health Science
Center at San Antonio

"Studies on the Anti-Fertility Effects of a Potent LHRH Inhibitory
Analog (Antagonist) in the Cynomolgus Monkey"

PARFR-303 -- Leonard J. Lerner, Ph.D., Jefferson Medical College of
Thomas Jefferson University, Philadelphia, Pennsylvania

"Investigation of FC 20340 As An Anti-Fertility Agent When
Administered Parenterally or Orally"

PARFR-304 -- Walter G. Wiest, Ph.D. and Chander P. Puri, Ph.D., Washington
University Medical School, St. Louis, Missouri

"Evaluation of Anti-Fertility Effects of a Potent LHRH Antagonist
in the Guinea Pig as a Preclinical Model"

PARFR-P55 (FINAL) -- Vladimir Petrow, Ph.D., D.Sc., Duke University Medical
Center, Durham, North Carolina

"1-Hydroxyestra-1,3,5(10)-TRIEN-17B-OLS and Congeners as Contra-
gestative Agents"

PARFR-P63 (FINAL) -- Antonio Scommegna, M.D., Michael Reese Hospital and
Medical Center, Chicago, Illinois

"Prostaglandin Antagonists as Local Antifertility Agents"

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III. ADMINISTRATIVE

- A. Most subagreements are executed on projects reviewed and approved at the 10/13-14/82 SAC Meeting.

IV. MISCELLANEOUS

- A. Dr. Zatuchni reports on the June 22, 23, 24, 1982 (Tuesday-Thursday) PARFR Workshop on "Non-Surgical Methods for Female Tubal Occlusion" to be held at the Ambassador East Hotel prior to the SAC Meeting. All speakers, moderators and participants have been invited and unfortunately, due to hotel space we are limited to a total attendance of 65.

ADJOURN: 3:30 P.M.

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PARFR SCIENTIFIC ADVISORY COMMITTEE

MEETING XXXIX

Friday, June 25, 1982

AMBASSADOR EAST HOTEL
1301 N. State Parkway
Chicago, Illinois 60610
(312) 787-7200

MINUTES

VOTING SAC MEMBERS PRESENT

John J. Sciarra, M.D., Ph.D.
Nancy J. Alexander, Ph.D.
David A. Blake, Ph.D.
Robert T. Chatterton, Ph.D.
Elizabeth B. Connell, M.D.
Joseph E. Davis, M.D.
Miriam H. Labbok, M.D., M.P.H.
Dean L. Moyer, M.D.
Rochelle N. Shain, Ph.D.
Aquiles J. Sobrero, M.D.

VOTING SAC MEMBER ABSENT

Kamran S. Moghissi, M.D.

PARFR STAFF PRESENT

Alfredo Goldsmith, M.D., M.P.H.
Diane Krier-Morrow, M.B.A.
Gerald I. Zatuchni, M.D., M.Sc.

USAID STAFF PRESENT

James D. Shelton, M.D., M.P.H.

The thirty-ninth meeting of PARFR's Scientific Advisory Committee convened on Friday, June 25, 1982 at 9:00 A.M. at the Ambassador East Hotel in Chicago, Illinois. Dr. John J. Sciarra presided as Chairman. Minutes of the March 13, 1982 meeting were approved.

I. ANNOUNCEMENTS

- A. Dr. Rochelle Shain was introduced as a new member for a three year term ending July, 1985.
- B. PARFR's offices are relocating next Monday, June 28, 1982 to:

Suite 1525
875 N. Michigan Avenue
Chicago, Illinois 60611

The telephone number remains the same: (312) 649-2990.

- C. The next SAC meeting will be held on Sunday, October 17, 1982 at the Hotel Californian, San Francisco.

The 1983 SAC meeting dates are: February 28, 1982 (Monday), Washington, D.C.
June 4, 1983 (Saturday), New Orleans, La.

q/b

I. ANNOUNCEMENTS (cont'd)

- D. The PARFR staff was congratulated on the organization and program content of our 12th International Workshop "Non-Surgical Methods for Female Tubal Occlusion," June 22-24, 1982 at the Ambassador East Hotel. Sixty-five persons attended, representing 14 countries.

II. NEW BUSINESS

A. EXTENSION PROPOSAL REVIEW

PARFR-312 -- Brij B. Saxena, Ph.D., D.Sc., Cornell University Medical College, New York, New York

"A Clinical Evaluation of the Subdermal Contraceptive Norethindrone Pellet - Continuation of PARFR-229"

Funding Requested: I - \$3,140, II - \$3,338, III - \$70,895

Length of Project: One Year

After careful discussion and consideration of the proposal and independent site visit evaluation by Dr. Moghissi, it was decided not to implement the Phase II clinical trials at this time until the drug release study is completed and a full report presented. Dr. Saxena will be advised to prepare a revised proposal for our October 17th SAC meeting. Approval for the preparation of the improved pellet was granted.

PARFR-212(85N) -- Milos Chvapil, M.D., Ph.D., The University of Arizona Health Sciences Center, Tucson, Arizona

"Development of Collagen Sponge Containing Spermicide and Post-Coital Testing of Collagen Sponge Diaphragm"

Funding Requested: \$4,648

Length of Project: One Year

The members approved Dr. Chvapil's request; however, advised the staff to inform Dr. Chvapil that no further extension on this project will be considered due to the fact that FDA granted marketing approval for the polymer - nonoxynol sponge and the data show that Chvapil's barrier method is not an improvement over this other development.

PARFR-304 -- Walter G. Weist, Ph.D. and Chander P. Puri, Ph.D.,

Washington University Medical School, St. Louis, Missouri

"Evaluation of Anti-Fertility Effects of a Potent LHRH Antagonist in the Guinea Pig as a Preclinical Model"

Funding Requested: \$6,704

Length of Project: 8/1/82-9/30/8

The Committee decided that the guinea pig model is not appropriate and the proposal does not merit continued support.

A. EXTENSION PROPOSAL REVIEW (cont'd)

PARFR-235SRI -- Richard L. Dunn, Ph.D., Southern Research Institute,
Birmingham, Alabama

"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the
Female Reproductive Tract - Continuation of PARFR-206SRI"

Funding Requested: \$69,937 -- Southern Research Institute
\$36,081 -- University of Alabama in Birmingham

Length of Project: One Year

The Committee approved a modified proposal dealing mainly with the develop-
ment of a 3-month norgestimate releasing ring with a release rate suffi-
cient to inhibit ovulation after 2 days of insertion and up to 90-95 days.
The Committee suggested that the baboon studies should be limited to
release rate.

PARFR-236IIT -- Rajendra G. Mehta, Ph.D., IIT Research Institute, Chicago,
Illinois

"Retinoids and Male Contraception"

Funding Requested: \$61,030 Length of Project: One Year

The Committee recommended not to approve funding of this project as pre-
sented.

PARFR-309 -- Raksha Mehta, Ph.D. and Robert T. Chatterton, Ph.D.,
Northwestern University Medical School, Chicago, Illinois

"Ovulation Inhibition by Anordrin"

Funding Requested: \$71,948 Length of Project: One Year

The Committee approved continuation of this study to continue to test
the inhibition of ovulation by anordrin in primates. It was recommended
that the PARFR staff rework and reduce the budget.

B. FORMAL PROPOSAL REVIEW

Prof. Tapani Luukkainen, M.D., Ph.D., University of Helsinki, Helsinki,
Finland

"Studies on the Effectiveness of a Progestin-Releasing Intracervical
Device"

Funding Requested: \$36,700 Length of Project: One Year

The Committee approved this proposal and recommended that Dr. Rochelle
Shain become involved in order to assist the principal investigator
with the acceptability component of the clinical trial.

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B. FORMAL PROPOSAL REVIEW (cont'd)

Lourens J.D. Zaneveld, D.V.M., Ph.D., University of Illinois, Chicago,
Illinois

"Efficacy of Quinacrine Pellets in the Primate"

Funding Requested: \$51,359 (Direct Cost Only)

Length of Project: One Year

The Committee approved the proposal with the addition of a tetracycline exposed group in order to assess the potential of this drug as a tubal occlusive agent. Also, the Committee suggested that this proposal should concentrate on effectiveness measured by histological changes and not, at this time, perform the pharmacodynamic (tissue level) quinacrine studies.

Danny H. Lewis, Ph.D., Stolle Research and Development Corporation,
Birmingham, Alabama

"Microcapsule Formulations for the Controlled Release of Spermicidal Agents"

Funding Requested: \$70,625

Length of Project: One Year

The proposal was not approved as presented; however, the Committee felt that the microencapsulated vaginal suppository is a novel approach and the group should work closely with Dr. Zaneveld (sperm acrosin inhibitors) in order to present a revised proposal to our 10/17/82 SAC meeting.

Mary V. Nekola, Ph.D., Tulane University School of Medicine, New Orleans,
Louisiana

"Prolonged Inhibition of Ovulation by LHRH Antagonists"

Funding Requested: \$63,277

Length of Project: One Year

This proposal was not approved for funding because the Committee felt that we should await NIH's determination on her proposal request to them and PARFR should save resources for clinical trials when an optimum analogue has been identified.

Duane L. Venton, Ph.D., University of Illinois, Chicago, Illinois

"Inhibition of Ovulation by Specific Antagonists of Prostaglandin F_{2a}"

Funding Requested: \$21,000 -- University of Illinois

\$38,136 -- Northwestern University

Length of Project: One Year

The Committee recommended no PARFR involvement until a specific compound is synthesized.

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B. FORMAL PROPOSAL REVIEW (cont'd)

Richard L. Dunn, Ph.D., Southern Research Institute, Birmingham, Alabama

"Development of a Fibrous IUD Delivery System for Estradiol/
Progesterone"

Funding Requested: \$65,972

Length of Project: One Year

The proposal was approved but the Committee, following Dr. Scommegna's evaluation (an independent evaluation) that the IND should not be prepared until the different prototypes have been evaluated by an independent group of referees and the best vector selected.

C. INFORMAL PROPOSAL REVIEW

Horacio B. Croxatto, M.D., Centro Nacional de la Familia, Santiago, Chile

"Progesterone Microcapsules"

Funding Requested: \$50,710

Length of Project: Fifteen Months

The Committee recommended a request for a formal proposal. The proposal should address, not only the clinical study as mentioned on the informal proposal, but also the progesterone delivery system.

D. TECHNICAL REPORT REVIEW

The following technical reports were reviewed:

PARFR-211 (FINAL) -- Joseph E. Davis, M.D., New York, New York

"Study of Vas Occlusion in Animals Using Chemical Agents"

PARFR-226C -- Rene Guzman-Serani, M.D., Universidad Austral de Chile,
Valdivia, Chile

"Clinical Trial of Fallopian Tubal Closure Using MCA"

PARFR-227B (FINAL) -- Hugo Maia, Jr., M.D., Maternidade Climerio de Oliveira,
Salvador, Bahia, Brasil

"Prostaglandin Levels in the Human Follicular Fluid in Relation to
the Moment of Ovulation"

PARFR-235UAB -- Lee R. Beck, Ph.D., University of Alabama in Birmingham,
Birmingham, Alabama

"A Fibrous Polymer for the Delivery of Contraceptive Steroids to the
Female Reproductive Tract - Continuation of PARFR-206UAB"

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C. TECHNICAL REPORT REVIEW (cont'd)

PARFR-237 (FINAL) -- Nancy J. Alexander, Ph.D., Oregon Regional Primate
Research Center, Beaverton, Oregon
"Detection of Pregnancy in Women Before Implantation"

PARFR-238C (FINAL) -- Rene Guzman-Serani, M.D., Universidad Austral de Chile,
Valdivia, Chile
"Radio-Opaque MCA - Cineflourography Study"

PARFR-240 -- Ralph M. Richart, M.D., Columbia University, New York, New York
"Data Collection and Analysis of MCA/FEMCEPT Clinical Trials
(Previously PARFR-200C)"

PARFR-301T -- Ricardo H. Asch, M.D., The University of Texas Health Science
Center at San Antonio, San Antonio, Texas
"A Clinical Evaluation of the Bioabsorbable Subdermal Contraceptive
Norethindrone Pellet Implant"

PARFR-302 -- Ricardo H. Asch, M.D., The University of Texas Health Science
Center at San Antonio, San Antonio, Texas
"Studies on the Anti-Fertility Effects of a Potent LHRH Analog
(Antagonist) in the Cynomologus Monkey"

PARFR-305V -- Itic Zigelboim, M.D., Maternidad "Concepcion Palacios",
Caracas, Venezuela
"Radio-Opaque Methylcyanoacrylate (MCA) Delivered Through Single
Application (FEMCEPT) Device"

PARFR-307 -- Lourens J.D. Zaneveld, D.V.M., Ph.D., University of Illinois
at the Medical Center, Chicago, Illinois
"Development of Sperm Enzyme Inhibitors as Vaginal Contraceptives -
Continuation of PARFR-204"

PARFR-308 -- Ronald W. Lewis, Ph.D., Tulane University, DRPRC, New Orleans,
Louisiana
"Transcutaneous Ablation of Cauda Epididymis in Non-Human Primates"

PARFR-310C -- Enrique Guiloff, M.D., Santiago, Chile
"MCA/FEMCEPT Video Study"

PARFR 313E -- Robert Snowden, Ph.D., Institute of Population Studies,
University of Exeter, Devon, England
"Uterine Measurement - Clinical Comparison Study (Wing Sound II)"

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III. ADMINISTRATIVE

A. The following subagreements are executed on projects reviewed and approved at the March 13, 1982 SAC meeting:

1. PARFR-315 -- Erwin Goldberg, Ph.D., Northwestern University, Evanston, Illinois
"Immunologic Suppression of Fertility by Synthetic Antigenic Determinants of Lactate Dehydrogenase-C₄, Extension of PARFR-232"
Funding Period: 3/1/82-2/28/83 Amount Funded: \$53,736
2. PARFR-317 -- Lourens J.D. Zaneveld, D.V.M., Ph.D., University of Illinois at the Medical Center, Chicago, Illinois
"Electroejaculation of Primates for Shug Evaluation and LDH Immunization"
Funding Period: 7/1/82-6/30/83 Amount Funded: \$11,948
3. PARFR-319 -- George A. Digenis, Ph.D., University of Kentucky, Lexington, Kentucky
"Development of Methodology for Following Microcapsule Trans-cervical Transport in Baboons Utilizing External Scintigraphy"
Funding Period: 7/1/82-12/31/82 Amount Funded: \$9,950
4. PARFR-321 -- John C.M. Tsibris, Ph.D., University of Illinois, Chicago, Illinois
"Guaiacol Peroxidase Levels: Predictions of Ovulation in Women"
Funding Period: 8/1/82-7/31/83 Amount Funded: \$27,391

B. The following technical information report was distributed to 6,000 research and medical libraries:

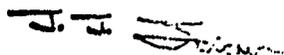
Vol. 2, No. 1 -- "Research Frontiers in Fertility Regulation"
"Current Status of Plant Products Reported to Inhibit Sperm"
Norman R. Farnsworth, Ph.D. and Donald P. Waller, Ph.D.

IV. MISCELLANEOUS

A. Dr. Zatuchni reported on the "Contraceptive Drug Delivery Systems" workshop which will be held in New Orleans, Louisiana at the Royal Orleans Hotel, May 31 - June 3, 1983.

There being no further business, the meeting adjourned June 25, 1982 at 3:00 P.M.

Respectfully submitted,



John J. Sciarra, M.D., Ph.D.
Program Director,
PARFR Chairman, Scientific Advisory Committee



Diane Krier-Morrow, M.B.A.
Director of Administration, PARFR

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