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19p.

SUBJECT: Evaluation of Activities of the Program for Applied Research on Fertility Regulation, PARFR, Northwestern University, AID/csd-3608.

This evaluation is based on the activities of the two project co-monitors (Speidel and Prager) which include weekly phone contacts, quarterly attendance and participation in the deliberations of the Scientific Advisory Committee and additional visits to the contractor for the conduct of other PARFR business and surveillance of project activities in fulfillment of contract objectives.

PARFR was initiated in June 1972 and has been in operation for four years. SAC reviewed the program after 18 months and 30 months. The present review at 48 months will emphasize the last 18 months of operation, i.e., November 1974 to June 1976.

PARFR is a continuing program which administers a subcontract research program for applied contraceptive research with the objective of developing new or improved means of fertility control suitable for use in the LDCs.

A small but efficient staff comprised of the Assistant Program Director, controller, and two part-time scientist-clinicians with considerable experience in family planning research and service projects both in the U.S. and in developing countries administers the program with the support of a scientific advisory committee, SAC, comprised of 10-12 scientists and clinicians who are themselves actively engaged in applied contraceptive research. By this combination of experience, expertise and flexible, efficient management, the Population Office is able to extend its research program to follow-up small but significant research leads and to draw on a broad range of research advisory talents on a regular basis.

PARFR Review and Critique

A. Scientific Program. The complete scientific program organized by broad research areas is presented in the Appendix along with a capsule summary of the status of research under each project. The program is summarized in the following table:



Research Area	Number of Projects		Total
	Good Leads	Terminated	
I Female Sterilization	3	5	8
II Female Pharmacological	5	7	12
III IUD	3	2	5
IV Female Local Methods	3	2	5
V Male Methods	4	4	8
VI Immunological Approaches	3		3
VII Pregnancy Termination	1		1
Total projects			42

Several different viable research leads are being pursued in each of the five major areas. Female Sterilization, in particular Hysteroscopy, has been systematically investigated in a coordinated research approach which included a Workshop on the subject (1973), funding of a select number of projects (3) to advance the state of hysteroscopic research, initiation by PARFR of a fourth project, the Hysteroscopic Registry PARFR 66, to assemble information on worldwide clinical experience with the method, and a follow-up Workshop on Female Sterilization in 1975. An approach utilizing uterotubal blocking devices (plugs) has advanced to the stage of human trials (PARFR 63, 87). In addition, a blind transcervical approach utilizing MCA, a tissue glue, about to be investigated in women, also looks very promising (PARFR 86).

Two approaches in the Female Pharmacological Area have been investigated, long acting systems for drug delivery and an investigation of new pharmacological agents. The three projects looking at different long-acting systems, while at various stages of development, still hold promise to produce a new method (PARFR 76-83, 68, 80). Of the eight different drugs or chemical agents systematically screened for possible fertility control, two remain as viable research leads, an end-organ specific chemical agent (PARFR 65) and an extract of the pineal gland which exhibits antigonadotropic activity (PARFR 67). Although the area of "drug screening" has not yielded a good track record, there was theoretical reason, at least, to believe that all of these drugs or agents would have anti-fertility effects. Through PARFR, these potential leads have been checked out quickly and at low cost to AID.

In the IUD area, PARFR is supporting studies of two different modifications to the IUD. With the addition of copper, PARFR is looking at use-effectiveness in Jamaica and the U.S. (PARFR 54), and effect on blood loss among users in Egypt (PARFR 82). In addition, IUDs releasing an antifibrinolytic agent EACA, are being studied (PARFR 81). Two other modifications proved to offer no advantage over inert IUDs and project support has terminated.

A most promising Female Local Method utilizing a collagen sponge, was supported first as a pilot study and is now being supported in a larger clinical trial of 140 volunteers (PARFR 85). Contrary to expectations, the sponge is odorless, can be worn for extended periods without discomfort, and appears to have high acceptability.

The most promising Male Method supported by PARFR is the transcuteaneous injection of sclerosing agents into the vas (PARFR 51). This method will be extended in another small trial by a second clinician before a larger clinical trial is initiated (PARFR-P7). Two new approaches to reversible male contraception are also being supported in pilot studies.

Recently PARFR has begun to support projects in two additional areas of fertility control, Immunology and Pregnancy Termination. A project investigating the role of antibodies in vasectomy and vasovasostomy (PARFR 70) has been particularly successful in developing new knowledge which should ultimately lead to improvements in vasectomy and be useful in other areas as well. Two new pilot studies in immunology are also being supported.

Pregnancy Termination, the least thoroughly investigated area, is deserving of more research support in the future. Only one project has been funded in this area, a study of the post-coital contraceptive effect of IUD insertion (PARFR 84).

Each of the five major areas have been investigated from a variety of approaches. A large number of leads have been checked out quickly and inexpensively. Several have produced useful technological advances and their further development is being actively pursued. Others have not panned out and have been eliminated. In addition, several other projects are developing valuable knowledge which will allow better utilization of existing fertility regulation methods.

B. Soliciting Research. PARFR continues to solicit research by an annual mailing of the Requests for Proposals, RFP, to a mailing list of 1750 U.S. and LDC individuals and institutions. A.I.D. supplements this mailing by requesting mission cooperation for the distribution of the RFP. In addition, the forum of national and international professional society meetings is utilized to advertise the program by exhibit, distribution of literature, and discussion with prospective investigators. Exhibits have been set up at the IUD meeting in Cairo, and the American Fertility Society Meeting in Los Angeles and are being planned in the near future for the FIGO Meeting in Mexico City and two additional international meetings.

The pattern of response to this approach of soliciting proposals has been an initial swelling in the number of proposals received followed by a gradual waning. (See Table 1). Apparently the reservoir of available, unfunded innovative ideas has been well tapped, and the scientific community, now more familiar with PARFR objectives, has become more selective in the types of proposals they submit to PARFR. The following additional strategies are being utilized to increase the number of proposals and projects for funding: 1) PARFR has recently placed advertisements in key scientific journals to reach a wider audience. Furthermore, PARFR staff is taking an increasingly active role in 2) initiating projects and identifying investigators to carry out research (eg. PARFR 66 and 84), and 3) linking clinicians with laboratories for the continuation of research initiated under the PARFR program (eg. PARFR P6). 4) The category of projects designated collaborative research between U.S. and LDC investigators was encouraged early in the life of the program to help generate research in LDCs. This has proven to be an ineffective approach and has been largely abandoned. In its place PARFR has utilized an approach of working closely with an LDC investigator to develop a project of mutual interest to PARFR and the investigator, as in the case of the Egypt blood loss study (PARFR 82). 5) An additional approach to involve LDC investigators is currently being pursued. A clinical test site will be arranged at an established facility in an LDC--El Salvador or Costa Rica is being considered--to carry out collaborative development of new contraceptive technology developed under the program. The prearrangement of the administrative mechanism including the committee for protection of human subjects at an overseas test site has the dual advantage not only of assuring overseas research but of increasing the efficiency of the scientific program.

C. Reviewing Proposals. The 2-step review of proposals continues to be an effective and efficient mechanism for PARFR and for the proposing scientist whereby only investigators proposing research which falls within the purview of PARFR and shows a high likelihood of being applied are requested to prepare formal proposals. This procedure assures more efficient use of the review time of SAC members, also. Overall, PARFR has selected about one-fourth of the informal proposals for formal application, and more than one-third of the formal proposals for funding.

D. Monitoring Projects. Funded projects are monitored closely by both PARFR and SAC by the following procedure, and PARFR periodically takes steps to strengthen this aspect of the program. SAC members who review proposals approved for funding, follow through with monitoring the ongoing projects. This entails reviewing semi-annual progress reports including the budget, filing written comments on the project's status, and participating in annual site visits of projects when possible. The PARFR staff also reviews thoroughly the

substantive reports as well as monthly expenditures and keeps close tabs on all projects. Finally the full SAC committee reviews each project at regular intervals. This review procedure has successfully kept many projects on track and allowed early identification of scientific problems and administrative irregularities. For example, two projects were terminated prematurely in part for irregularities. Scientific problems were identified with PARFR 80 and corrected as a result of close monitoring.

A new feature will be added to the monitoring phase. Since the SAC often raises questions in the course of project review that are not dealt with in progress reports, it was decided to invite investigators to discuss their projects with a full SAC committee. It is anticipated that this approach will obviate the tendency to second-guess investigators, particularly critical when decisions are made regarding continuation or termination and will allow investigators to benefit by the experience of a panel of experts, as well as to be educated as to the objectives of PARFR. This meeting is being arranged for the September SAC meeting.

E. Utilizing and Disseminating Research Results. There are several methods by which PARFR utilizes and disseminates research results.

- 1) PARFR organizes annual workshops on timely topics of scientific interest and of programmatic interest to A.I.D. The third workshop carried out during the period of this review was on the subject of Female Sterilization Techniques. Some 70 participants from approximately 12 countries met in Minneapolis, Minnesota, June 15-17, 1975, to review the state of the art and discuss avenues of needed research. The Proceedings of this workshop were published in hardback and will be distributed widely by A.I.D., PARFR and AVS as well as made available for sale to the scientific community.
- 2) PARFR encourages all of its subcontractors to publish the results of research supported by PARFR. Where the investigator is disinclined to publish negative results, PARFR staff plans to prepare a manuscript for publication. This situation has arisen in the case of PARFR 71N.
- 3) With the establishment of a collaborative clinical research center in an LDC, new technological developments can more efficiently be tested on a human population of a size intermediate between that available to the investigator in his own institution and worldwide trials of the type conducted by IFRP. This should be an important contribution toward speeding the utilization of scientific results developed under the program.

F. Administrative Overhead. The administrative costs for the conduct of this program are extremely low relative to the total costs of the program (a concern raised during the last RAC review). During FY 76, only 16 percent of expenditures were for administrative costs, including PARFR staff salaries, overhead, consultant fees and travel for SAC meetings, and site visits. Of the \$885,000 expended and committed in FY 76, more than \$742,000 was for subcontracts, workshops and publications, the scientific output of the project. The technical project monitors are satisfied that this distribution of expenditures between administration and program is very favorable for A.I.D.

To PARFR's credit, the contractor periodically reviews its own organization, procedures, and accomplishments and initiates changes to increase program effectiveness and efficiency. In February 1976, PARFR undertook a more formal review involving its staff, A.I.D., and selected SAC members. Several important policy and procedural decisions were made. Steps have been taken to implement them, and these have been discussed in this review. In addition, the composition of the SAC was reviewed in terms of the expertise represented by the current membership and needs for additional skills in response to the types of proposals received by PARFR. Four SAC members will be replaced as of the September meeting.

G. Problem Areas.

- 1) The PARFR program is currently understaffed in terms of technical staff. In the past review period, the program has operated with one and for the past six months two part-time scientists. This has proven to be inadequate staffing to conduct more than routine scientific business. The output in terms of initiating projects and following through on research actions has been lower than anticipated and lower than necessary to drive an effective research program. To cope with this problem, the staffing plan has been restructured and additional scientific staff are actively being recruited.
- 2) A.I.D. and PARFR have been aware and concerned throughout the life of this project of the scarcity of fundable proposals from LDCs and PARFR has made strenuous efforts to involve LDC investigators by the means presented in this review. RAC recommended that PARFR pursue active recruitment among foreign students currently in this country as potential grantees upon their return to their home countries and this provision was written into the contract renewal amendment. PARFR has not yet investigated the feasibility of the possible source of foreign grantees.
- 3) A.I.D. travel restrictions have made it difficult for A.I.D. staff to fully participate in all SAC review and other planning meetings. It is very much in A.I.D.'s interest that both of the A.I.D. project monitors participate in these meetings particularly where decisions are made regarding funding proposals and continuing or terminating projects.

Invariably A.I.D. is called upon to clarify A.I.D. and PMA/POP policy and issues arise which require A.I.D. follow-up with various AID/W offices or USAID missions. For effective monitoring as well as for an effective project, continual A.I.D. participation in these meetings is mandatory.

cc: Research Division Staff
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Table 1

Summary of Proposal and Project Activity by CY

	CY 72 (6 months)	CY 73	CY 74	CY 75	CY 76 (to date)	Total
Informal Proposals	98	133	70	37	27	365
Formal Proposals	38	32	12	11	14	107
Funded Projects	13	14	3	4	8	42

APPENDIX

PARFR Research Program

I. Female Sterilization

A. Hysteroscopy

PARFR-63 - Development of a Reversible and Permanent Uterotubal Blocking Technique by Hysteroscopy - Hosseinian, University of Chicago

Hysteroscopic uterotubal plugs have prevented pregnancy in baboons without actually plugging the tubes. Two pregnancies have occurred among six baboons bred a total of 26 times after plugs were removed. Five baboons with devices in place will be followed for long-term effects.

PARFR-87N - Development of a Safe and Effective Hysteroscopic Sterilization Technique by using Uterotubal Blocking Devices - Hosseinian, Reza Pahlavi Medical Center, Iran; and Valle, Northwestern University

Extension of PARFR-63 in human clinical trials in Iran.

PARFR-66 - Collaborative Study on Hysteroscopic Sterilization Procedures - Richart, Columbia University

A Hysteroscopic Sterilization Registry gathered retrospective data from ten collaborators on 773 patients who underwent the procedure, 524 of whom were subsequently tested for tubal patency. There was an overall failure rate of 35.5 percent (patent tubes plus pregnancies) after the first procedure, 3.2 percent major complication rate including perforations, bowel damage, peritonitis, ectopic pregnancies and one death.

PARFR-61 - Development of a Hysteroscopic Technic for Permanent Sterilization - Dmowski, Michael Reese Medical Center, Chicago

Project to determine ideal time and temperature for thermocautery via hysteroscopic technic to occlude UTJ in baboons. Inadequate thermal electrode equipment caused project to fall behind schedule. Terminated.

PARFR-73 - Development of a Temperature Sensing Electrocautery Probe for Transcervical Sterilization - Falb, Battelle

Design, construction and evaluation of a hysteroscopic electrocautery electrode with a temperature sensor which can be inserted into the tissue surrounding the electrode tip for the purpose of defining the endpoint of hysteroscopic sterilization by cautery. Project completed.

B. Other Transcervical Approaches

PARFR-86N - Clinical Trial of Single Application Fertility Regulating (SAFR) Device - Bolduc and Richart, Population Research, Inc., Minneapolis

Phase I clinical trials of the SAFR device for the transcervical blind delivery of methylcyano-acrylate (MCA), a strong tissue glue, to the oviduct will be conducted in 200 women in five overseas sites. Project under negotiation.

PARFR-78 - Development of an Injectable Polymer System for Tubal Occlusion - Nuwayser, Abcor, Inc.

Polymeric systems composed of silicone, polylactide and quinacrine were evaluated for sterilization by injecting into oviducts of rabbits. Zero pregnancy resulted whenever a plug was found in the tube. Project expired.

PARFR-77 - Development of an Intrauterine Sterilizing Device - Diamond, University of Hawaii

Biodegradable sclerosing intrauterine devices containing quinacrine inserted into monkeys and baboons failed to produce tubal blockage as evaluated histologically although measurements of patency using perfusion techniques showed obstruction. Project terminated.

II. Female Pharmacological Approaches

A. Long Acting Systems

PARFR-76, 83 - Studies to Test an Injectable Delivery System for the Sustained Release of Norethisterone - Beck, University of Alabama

Experiments in rats and rabbits have shown that diffusion of norethisterone across the Polin Membrane is controlled at a constant rate, independent of concentration within the carrier, and successfully induced a state of infertility for long periods. Project to be extended to primates to maintain infertility for 90 days.

PARFR-68 - Potential Role of Crystalline Estradiol Implants for Sustained Ovarian Inhibition in Humans - Greenblatt, Medical College of Georgia

Estradiol implants (at six month intervals) have elevated blood estradiol levels and prevented ovulation. Oral progesterone brings on monthly menses. Method has high patient acceptability. Two pregnancies. Stepwise reduction of amount of estradiol from 100 mg will continue.

PARFR-80 - Fertility Control Through Local Cervical Injection of Micro-Encapsulated Progestins - Keller, Washington University

Microcapsules containing progesterone were prepared and injected daily into the cervix of cows. In vitro tests of cervical mucous demonstrated a significant difference in sperm migration when progesterone samples were compared to pre- and post-treatment samples. Project to continue for obtaining longer release rates and further animal testing.

B. New Pharmacologic Agents

PARFR-65 - Synthesis, Biochemistry and Biological Testing of End-Organ Specific Anti-Fertility Agents - Wotiz, Boston University

Sufficient quantities of a synthetic anti-implantational agent have been synthesized to begin toxicity studies. LD₅₀ studies in rats have shown no toxicity.

PARFR-67 - Effects of a Pineal Antigonadotropin on Ovulation, Implantation and Pregnancy - Orts, Oklahoma State University

A 3-peptide antigonadotropin extracted from bovine pineal glands partially inhibited the pre-ovulatory LH surge in rats. Research continuing.

PARFR-56 - Pharmacologic Acceleration of Ovum Transport as a Contraceptive Method - Pauerstein, University of Texas

The time course of ovum transport in monkeys and baboons was carefully documented in order to study the effect of estrogen on tubal transport. However, preliminary experiments failed to induce classic "tube-locking" of ova as described in other lab species. Terminated.

PARFR-60 - Fertility Control by Thyrotropin Releasing Hormone - Bienzenski, University of Illinois

Oral administration of TRH to 24 normally cycling healthy females failed to suppress ovulation. Terminated.

PARFR-75 - Testing the Antifertility Effects of Equilenin and Derivatives In Vivo - Bransome, Medical College of Georgia

Equilenin has to be administered in unacceptably high doses to inhibit progesterone synthesis in rats and thereby exhibits estrogenic effects. Administration of equilenin early in the cycle of rhesus monkey appears to be successful both in suppressing progesterone levels and preventing ovulation. No plans to continue project at present.

PARFR-52 - The Effect of Certain Indonesian Herbs on Early Pregnancy - Dickson, Washington State University

An Indonesian herb mixture administered to rats and rabbits had no antifertility effect. Terminated.

PARFR-59 - Bio-Assay of Luteolytic Agents Using Human Corpora Lutea - Bartosik, New York Medical College

Technical problems prevented the successful development of the human corpora luteum in vitro screen for luteolytic compounds. Terminated.

PARFR-64 - Contraceptive Action of Diethylaminoethanol - Ketchel, Oak Ridge Associated Universities

Neurotoxic side effects and an unacceptable pregnancy rate were observed in 17 female baboons, demonstrating that DEAE has no potential as a contraceptive agent in man. Terminated.

PARFR-71 - Inhibitors of Estrogen Biosynthesis in Fertility Regulation - Siiteri, University of California, San Francisco

Enzyme inhibitors of estrogen biosynthesis, Teslac and triene, did not reduce ovarian estradiol sufficiently to interfere with tubal transport or implantation in rats. Project terminated.

III. IUD

PARFR-54 - Evaluation of Loops C and D with Copper Comparing Results in a Developed and a Developing Country

No pregnancies have occurred in over 5600 women-months of use of the copper clad lippes loop; however, copper has not reduced pain and bleeding. Follow-up during second year of use will continue.

PARFR-81N - Clinical Evaluation of Intrauterine Devices Containing Epsilon Aminocaproic Acid (EACA) - Tauber, University of Essen, Germany

Project to demonstrate qualitative or quantitative change in menstrual blood loss in women utilizing an IUD incorporating an antifibrinolytic agent and to evaluate effect, if any, on peripheral antifibrinolysis. Project began 5/1/76; no results to date.

PARFR-82N - The Measurement of Blood Loss in Women Fitted with Copper-Clad and Standard Lippes Loopes in Cairo, Egypt - Hefnawi, Al-Azhar University, Egypt

More than 200 women have been enrolled out of a target of 350 in a single blind study of blood loss associated with wearing an IUD. Women are randomly assigned to either the standard loop or copper-clad loop. No comparative results are yet available.

PARFR 55 - Clinical Evaluation of a Long-Term Intrauterine Drug Delivery System Based on a Fluid-Filled IUD - Margolis, University of California, San Francisco

A fluid-filled IUD was found to offer no advantages over other IUDs. Terminated.

PARFR-69 - Contraceptive Action of 6-Dehydroretroprogesterone Delivered to the Uterine Cavity Via a Silastic T

A high pregnancy rate and unimproved pattern of pain and bleeding suggest that intrauterine retroprogesterone is inferior to progesterone as a contraceptive system. Project to terminate.

IV. Female Local Methods

PARFR-P2, P3 - Collagen Sponge Complex as a Contraceptive: Section I, Laboratory Studies; Section II, Clinical Studies, Chvapil, University of Arizona

The collagen sponge material can successfully bind (physically entrap) and release B-estradiol and progesterone. A collagen sponge (without drugs) was evaluated in 27 volunteers and found to be without irritation, odor, and discomfort to women or their sexual partners.

PARFR-85N - Collagen Sponge Contraceptive: Testing of Efficacy in Human Volunteers - Chvapil, University of Arizona

Expansion of human trials to study 1) sperm penetration in 40 volunteers using the collagen sponge contraceptive and 2) efficacy for delayed conception in another 100 volunteers.

PARFR-53 - The Use of Physiologically Non-toxic Organosiloxane and Fluorochemical Liquids as Intravaginal Spermatozoon Trapping Mechanisms - Graham, University of Minnesota

A good trapping compound was identified but did not have a good anti-fertilization effect when tested in rabbits. Terminated.

PARFR 58, 72 - Improving the Effectiveness of Vaginal Contraceptive Creams or Jellies by Addition of Sperm Enzyme Inhibitors - Zaneveld, IITRI

A sperm enzyme inhibitor, NPGB, when added to Delfin, was found to enhance its contraceptive effect. Terminated.

V. Male Methods

A. Sterilization

PARFR-51 - New Method for Obstructing the Vas Deferens by Direct Injection of Chemical Agents - Coffey, Johns Hopkins School of Medicine

The transcutaneous injection of sclerosing agents, ethanol and formaldehyde, into the vas caused permanent sterilization in ten men.

PARFR-P7 - A New Method for Obstructing the Vas Deferens by Direct Injection of Chemical Agents: A Non-operative Technique of Male Sterilization - Davis, New York Medical College

Results obtained by Coffey in PARFR-51 to be confirmed by another clinician in another ten men prior to investigating this method in a wider clinical trial.

B. Reversible Methods

PARFR-P5 - Contraceptive Effect of Low Oral Doses of 2,6-cis-Diphenylhexamethylcyclotetrasiloxane in the Male - Crabo, University of Minnesota

This project will investigate the minimal effective dose of 2,6-cis to inhibit fertility in the male rat and rabbit and to study reversibility. This new substance is superior to other anti-androgens in that it can be administered orally. Project being negotiated.

PARFR-P6 - Development and Evaluation of a Reversible Vas Deferens Blocking Device - Zaneveld, University of Illinois

Vas blocking device consisting of silicone plug held in place by a sheath applied to the outside of the vas will be evaluated in 20 rabbits. Project being negotiated.

PARFR-57 - Development of a Reversible Male Contraceptive Technique - Swartwout, University of Chicago

A Y-valve inserted in the vas of rats and rabbits sufficiently altered the vas that a normal ejaculate could not be delivered. Terminated.

PARFR-62 - Reversible Suppression of Male Fertility by Implants Located at the Vas Deferens - Hooker, Worcester Foundation

Copper wire implants in male rats and rabbits produced limited anti-fertility effect and reversibility was not impressive. Terminated.

PARFR-74 - Pharmacological Male Contraception - Kedia, University of Minnesota

Pharmacological agents Bethanidine, Guanethidine, and Bretylium administered to laboratory animals confirm the elimination of sperm from the ejaculate in mating experiments. Project terminated.

C. Condoms

PARFR-50 - Acceptability and Use-Effectiveness of Condoms - Okagaki, University of Minnesota; Jichi University, Japan

Some 300 Japanese couples were enrolled in a condom study comparing condoms of two different thicknesses. Preliminary results indicated no differences in use-effectiveness or preference. Project terminated.

VI. Immunology

PARFR-70 - Vasectomy: Role of Antibodies - Alexander, Oregon Regional Primate Research Center

Serum anti-sperm antibody levels are not important with respect to the return of fertility after vasovasostomy, but seminal plasma anti-sperm antibodies may be important because sperm are exposed to these antibodies. Research will continue and is expected to provide useful information concerning immunization of males or females with sperm antigens.

PARFR-P1 - Secretory Immune Response of the Female Genital Tract - McClurg, University of Nebraska Medical Center

This project aims to stimulate the genital tract secretory immune response to sperm in the female guinea pig with the objective of inhibiting fertility. Presence of sperm antibodies will be correlated with fertility data. No experimental results reported to date.

PARFR-P4 - Active Immunization of the Human with Follicle Stimulating Hormone to Inhibit Gonadal Function - Parlow, Harbor General Hospital

Purified sheep FSH will be prepared and injected in six women to produce antibodies to FSH. Evaluation by rat bioassay and patient response (serum estradiol and progesterone levels). Project being negotiated.

VII. Pregnancy Termination

PARFR-84N - Further Evaluation of the Copper T Intrauterine Contraceptive Device as a Postcoital Method of Contraceptive - Lippes, Deaconess Hospital, Buffalo

The copper T IUD will be evaluated as a postcoital method of contraception in 1000 women at five centers in the U.S.