

PROJECT EVALUATION SUMMARY (PES) - PART I

1. PROJECT TITLE Program for Applied Research on Fertility Regulation (PARFR)			2. PROJECT NUMBER 932-0546	3. MISSION/AIC/W OFFICE DS/POP/R
4. EVALUATION NUMBER (Enter the number maintained by the reporting unit e.g., Country or AIC/W Administrative Code, Fiscal Year, Serial No. beginning with No. 1 each FY) <i>21-45</i> <i>8-21-81</i>			<input type="checkbox"/> REGULAR EVALUATION <input checked="" type="checkbox"/> SPECIAL EVALUATION	
5. KEY PROJECT IMPLEMENTATION DATES			6. ESTIMATED PROJECT FUNDING	7. PERIOD COVERED BY EVALUATION
A. First PRO-AG or Equivalent FY <u>72</u>	B. Final Obligation Expected FY <u>85</u>	C. Final Input Delivery FY <u>86</u>	A. Total \$ <u>9.6 million</u> B. U.S. \$ _____	From (month/yr.) <u>May 1972</u> To (month/yr.) <u>Dec 1980</u> Date of Evaluation Review <u>Dec 1980</u>

8. ACTION DECISIONS APPROVED BY MISSION OR AIC/W OFFICE DIRECTOR

A. List decisions and/or unresolved issues and those items needing further study. (NOTE: Mission decisions which anticipate AIC/W or regional office action should specify type of document, e.g., program, SPAR, PIC, when will present decision request.)	B. NAME OF OFFICER RESPONSIBLE FOR ACTION	C. DATE ACTION TO BE COMPLETED
This evaluation serves as a basis for initiating a new five-year phase of the project, FY1981-FY1985. A project review and site visit should be conducted in Dec 1982.	DS/POP/R, M. Mamlouk	Dec 1982

BEST AVAILABLE DOCUMENT

9. INVENTORY OF DOCUMENTS TO BE REVISED PER ABOVE DECISIONS			10. ALTERNATIVE DECISIONS ON FUTURE OF PROJECT	
<input checked="" type="checkbox"/> Project Paper	<input type="checkbox"/> Implementation Plan e.g., CPI Network	<input type="checkbox"/> Other (Specify) _____	A. <input type="checkbox"/> Continue Project Without Change	
<input type="checkbox"/> Financial Plan	<input type="checkbox"/> PIC/T	<input type="checkbox"/> Other (Specify) _____	B. <input checked="" type="checkbox"/> Change Project Design and/or	
<input type="checkbox"/> Logical Framework	<input type="checkbox"/> PIC/C		<input type="checkbox"/> Change Implementation Plan	
<input type="checkbox"/> Project Agreement	<input type="checkbox"/> PIC/P		C. <input type="checkbox"/> Discontinue Project	

11. PROJECT OFFICER AND HOST COUNTRY OR OTHER RANKING PARTICIPANT'S AS APPROPRIATE (Name and Title)	12. Mission/AIC/W Office Director Approves
(for intensive evaluations only)	Signature <i>J. Speidel</i>
Signature, DAA/DS/HRD	Typed Name J. Joseph Speidel (Acting)
	Date 8-21-81

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II. SUMMARY OF THE EVALUATION

It is clear that the PARFR employs a staff with considerable expertise, dedication, enthusiasm, and commitment to the objectives of the program.

To date, 137 projects have been funded. Nearly all are preliminary studies designed to probe or explore topics of interest. (These research projects are grouped in the seven categories listed at the end of Chapter I.) For 34 of the projects which have sufficient promise, final preclinical or early clinical trials are planned. The majority of these more promising projects--approximately 80 percent--are unique to the PARFR. They are not being supported by any other grant agency. If after further development the fertility regulation methods prove to be effective, their use in developing countries should be considered.

The projects for which clinical tests are scheduled to begin fulfill the stated priorities of the PARFR. It has not been possible to develop projects on contraceptive methods that emphasize specific methods of delivery or use.

The range of approaches is broad, and there is a reasonable balance of contraceptive methods. There is no unnecessary duplication of projects supported by other funding agencies. Certain areas of fertility research have not been covered by the PARFR because they have been funded by other grant agencies (e.g., IFRP, WHO, and NIH).

The principal investigators for the two subcontracted projects in Chicago are competent. Staffing and laboratory facilities are adequate. The research designs and plans reflect consideration of the projects' objectives.

Clinical and Laboratory Research

The PARFR is attempting to conduct as much as possible clinical and laboratory research in LDCs. Twenty-one projects have been initiated in 10 countries. Because most projects are about to begin clinical trials, investigators in LDCs are planning to do more investigative work.

PARFR staff have visited many sites for proposed clinical tests in LDCs. AID's restrictions, political problems, and investigators' commitments to other agencies such as the WHO have created difficulties in certain countries.

Subcontracts

Initially, a widespread request for proposals for subcontracts was issued. One-year subcontracts are being awarded now for existing projects for which actual trials in the field may begin in the near future. The projects vary in size. Funding for one year appears to be appropriate although the investigators are constrained, more so because clinical trials are being planned.

The Scientific Advisory Committee

The composition of the Scientific Advisory Committee (SAC), the tenure of SAC members, and the mechanism for decisionmaking have been cause for serious concern. Each member of the SAC has a good scientific background; however, considered as a whole, the committee has a disproportionate number of ob/gyn clinicians. Considering the current range of topics, there is a lack of expertise in certain areas and a consequent lack of competent advice on all proposals. For example, there is no pharmacologist, polymer chemist, or toxicologist on the SAC. Few of the members have experience performing clinical trials of drugs. No statistician or epidemiologist is on the committee. However, consultants in different fields have been used for ad hoc projects.

In view of the composition of the committee, there may be a conflict of interest. The director of the program is also the chairperson and a voting member of the SAC. Several members of the SAC have received or are now receiving funds from the PARFR--a cause for concern, even though these members excuse themselves from the room when their projects are being discussed and abstain from voting.

The frequency of meetings (three times per year) appears to be appropriate, although the one-day agenda is crowded and there may not always be sufficient time for adequate review. The projects appear to be monitored quite well by PARFR staff who visit each project at least once a year. The entire SAC formally reviews each project at least once a year. The principal investigator submits progress reports semi-annually or more frequently.

The ethical aspects of all proposals are fully covered and the subjects' rights appear to be well protected. Informed consents are included in all proposals involving human subjects. These consent forms conform to the guidelines of the Department of Health and Human Services (DHHS). Each project must be approved by its own institutional review board (IRB), and by the IRB of Northwest University--an apparently redundant and therefore unnecessary requirement for U.S. institutions that have the general assurance of the DHHS.

PARFR's Relationships with Other Agencies

The relationship between the AID project officer and PARFR appears to be good at this time. The evaluation team was unable to fully explore the method AID used to monitor the program. It seems that the one program officer has most of the responsibility and makes most of the decisions. Staff of the PARFR seem to have good relationships with other funding agencies, such as the IFRP, NICHD (CPR), WHO, and the Population Council (ICCR). In the past, these organizations held annual meetings. Meetings now are scheduled biennially. Contacts during the year are frequent, and administrators of the programs meet informally at scientific meetings. There appears to be little overlap in the projects funded by the PARFR and other agencies. The PARFR and the IFRP have established an excellent, cooperative relationship that is of particular interest and importance. The PARFR institutes Phase I and Phase II clinical tests. If these are successful, Phase III testing is taken over by the IFRP. This division of responsibility allows the two agencies to use their respective expertise and funds without duplicating each other's effort.

Publications

Despite its small staff, the PARFR has undertaken a monumental effort to publish information on the development and status of methods of fertility regulation. Particular emphasis is given to methods in PARFR projects. In addition, the PARFR sponsors international workshops at frequent intervals and publishes the proceedings of those workshops rapidly in excellent format. However, distribution to workers in the field in the U.S. and abroad is limited.

PARFR's newest publication, Research Frontiers in Fertility Regulation (RFFR) is particularly valuable; it contains current reviews of various fertility regulation methods that are written by authorities in the field. These reports supplement existing publications and provide new, and previously unavailable, information.

Staffing and Location

PARFR staff are highly motivated and well organized. The size of the staff is small. Some positions are vacant and additional staff are urgently needed.

The space available to staff is small, given the size of the operation, but the location is good; it allows the director of the project, the chair-

person of Ob/Gyn at Northwestern, to spend sufficient time with the administrative staff. Furthermore, affiliation with the university lends prestige to the entire project. University officials have expressed their full support to the project. The hospital now rents space to the PARFR for a modest fee. This has resulted in considerable savings to the PARFR, for indirect costs to the university are calculated at the lower off-campus rate.

Funding

In the opinion of the evaluation team, the PARFR has the capacity to use effectively the funds it has requested for the next five years. If funding were to be curtailed, some promising and worthwhile projects would have to be terminated. The team believes that all the projects that have been proposed are worthy of further study and could result in the development of useful methods of fertility regulation that could supplant or augment existing methods. If full support to develop these new methods is awarded, more administrative staff could be hired and additional office space could be acquired.