

AGENCY FOR INTERNATIONAL DEVELOPMENT <b>PROJECT DATA SHEET</b>	1. TRANSACTION CODE <input type="checkbox"/> A = Add <input type="checkbox"/> C = Change <input type="checkbox"/> D = Delete	ISN: 90100 Amendment Number 1	DOCUMENT CODE 3
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2. COUNTRY/ENTITY Interregional	3. PROJECT NUMBER 936-3005
4. BUREAU/OFFICE S&T/POP	5. PROJECT TITLE (maximum 40 characters) Population Council Program

6. PROJECT ASSISTANCE COMPLETION DATE (PACD) MM DD YY 06 30 89	7. ESTIMATED DATE OF OBLIGATION (Under "B" below, enter 1, 2, 3, or 4) A. Initial FY 78 B. Quarter <input type="checkbox"/> C. Final FY 87
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8. COSTS (\$000 OR EQUIVALENT \$1 = )						
A. FUNDING SOURCE	FIRST FY			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total <sup>a/</sup>
AID Appropriated Total	3,300		3,300	36,286		36,286
(Grant)	( 3,300 )	( )	( 3,300 )	36,286 )	( )	( 36,286
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S.	1. <input type="checkbox"/>					
	2. <input type="checkbox"/>					
Host Country						
Other Donor(s)						
<b>TOTALS</b>	3,300		3,300	36,286		36,286

9. SCHEDULE OF AID FUNDING (\$000)									
A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE		D. OBLIGATIONS TO DATE <sup>a/</sup>		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT <sup>a/</sup>	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1) PN	440	400		11,410		9,986		36,286	
(2)									
(3)									
(4)									
<b>TOTALS</b>				11,410		9,986		36,286	

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)	11. SECONDARY PURPOSE CODE
12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)	
A. Code	
B. Amount	

13. PROJECT PURPOSE (maximum 480 characters)

Improved delivery and use of family planning services in developing countries.

14. SCHEDULED EVALUATIONS Interim MM YY 10 83 Final MM YY	15. SOURCE/ORIGIN OF GOODS AND SERVICES <input checked="" type="checkbox"/> 000 <input type="checkbox"/> 941 <input checked="" type="checkbox"/> Local <input type="checkbox"/> Other (Specify) 935
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16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a \_\_\_\_\_ page PP Amendment.)

<sup>a/</sup> Includes \$9,100,000 obligated under authorization for the period FY 78 - FY 82. New cumulative authorization is \$36,286,000.

17. APPROVED BY	Signature  Title Director, S&T/POP	Date Signed MM DD YY 10 12 89	18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION MM DD YY
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PROJECT AUTHORIZATION AMENDMENT

Name of  
Country/Entity: Interregional

Project Title: Population Council  
Program

Project No. : 936-3005

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize an increase not to exceed \$9,986,000 in the level of funding of the centrally funded Population Council Program to a new life-of-project total of \$36,286,000 in grant funds for the period FY 1978 - FY 1987. Funding during the remaining three-year period FY 1985 - FY 1987 will be in annual increments, subject to the availability of funds in accordance with A.I.D. OYB/allotment process, to help in financing foreign exchange and local currency costs for the project.

2. The project has two parts: (a) annually determined support to selected subprojects proposed by the Population Council or designed by A.I.D., including activities in contraceptive development, contraceptive introduction, and family planning field projects and (b) technical and financial assistance to the Tunisian national family planning program. The increase will support additional activities under part (a).

3. The cooperative agreements which may be negotiated with The Population Council and executed by the officer to whom such authority is delegated in accordance with A.I.D. regulations and Delegations of Authority shall be subject to the following terms and conditions together with such other terms and conditions as A.I.D. may deem appropriate.

4. Source and Origin of Commodities, Nationality of Services

a. Commodities financed by A.I.D. under the project shall have their source and origin in the cooperating country\* or the United States, except as A.I.D. may otherwise agree in writing. Except for ocean shipping, the suppliers of commodities or services shall have the cooperating country or the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

b. The aggregate cost of all goods and services procured under each subagreement in a cooperating country may not exceed \$750,000.

\*Each cooperating country where research, training, technical, or other assistance takes place under the project shall be deemed to be a cooperating country for the purpose of permitting local cost financing of goods and services for the activity being conducted in such country. Such activities may be undertaken in any country included in A.I.D. geographic code 935.

2



ACTION MEMORANDUM FOR THE ADMINISTRATOR

JUN 26 1985

THRU: AA/PPC, Richard A. <sup>Richard A. Derrham</sup> Derrham  
FROM: S&T, N. C. Brady <sup>for</sup>  
SUBJECT: Increased Authorization of the Population Council  
Project 936-3005

Action: Your approval is required to increase the authorization of the Population Council Project 936-3005 from \$26,300,000 to \$36,286,000 to support additional activities, particularly contraceptive development.

Discussion: Project 936-3005 was originally funded from FY 78 to FY 82 and then, following the approval of a new Project Paper, was extended for a five-year period under two Cooperative Agreements with the Population Council: the Population Council Program Subproject (DPE-3005-A-00-3003-00) and the Tunisia Subproject (DPE-3005-A-00-1049-00). Under The Population Council Program Subproject, the Agency has a Cooperative Agreement with the Council to support a number of important family planning activities, including contraceptive development, contraceptive introduction and family planning field projects. Under the Tunisia Subproject, the Population Council has provided assistance and program resources to the Government of Tunisia, primarily for family planning outreach during a period when there was no bilateral program with that country. Final authorized funding for the Tunisia Subproject was provided in FY 85. Final authorized funding for the Population Council Program Subproject will be added in FY 87.

As one of the Agency's primary vehicles for contraceptive development, the obligations for the Population Council Program Subproject are now well ahead of the original schedule (see attached Table). The reasons for this are two-fold. First, a number of the projects funded under this Agreement have and are continuing to proceed more rapidly than originally expected. In addition, other activities which had not been anticipated at

the beginning of the Agreement, but which are within the workscope of the Project Paper and Cooperative Agreement, have opened up for funding. Therefore, in order to continue the trajectory for the contraceptive development activities in this project, an increase in authorization is required. The increased activities which are proposed will be done within the same time-frame as originally planned. This request to increase support for the Population Council Program is consistent with the Agency's new directive and priority for contraceptive development research.

Some of the expected activities are discussed below.

1. Increased support is needed for development and introduction of NORPLANT<sup>®</sup> subdermal implants. This includes support for four U.S. sites, three ongoing and one new site, which are conducting studies leading to a New Drug Application (NDA) with the FDA for the NORPLANT<sup>®</sup> two-rod system. Equally important, preintroduction activities in a number of developing countries for the NORPLANT<sup>®</sup> six-capsule system are progressing much more rapidly than previously anticipated and could benefit from additional funds.
2. Additional funding for two U.S. clinical sites for evaluation of the levonorgestrel IUD and for toxicology studies is required for submission of an NDA for this method.
3. The isolation and purification of hormone inhibin is proceeding rapidly. Amino acid sequencing is being carried out with the aim of cloning the material in the near future. This protein provides a possible new male method of contraception as well as having potential application for women.
4. The isolation and purification of an ovarian factor called Gonadotropin-Surge Inhibiting Factor (GnSIF) is proceeding on schedule. This newly described protein may offer the potential for a completely new form of contraception for women.
5. Unanticipated adverse effects on serum lipids caused by the Contraceptive Vaginal Ring (CVR) in its current formulation have recently been described. New formulations with variable ratios of progestin and estrogen need to be explored. In addition, a progesterone ring which can be used in lactating women has shown promise in early clinical studies and could benefit from increased funding.

6. New initiatives - The Population Council conducts probing studies and otherwise identifies good candidates for contraceptive development. We anticipate potential support for these projects as they arise.

Agency Policy: The project will continue to be implemented in accordance with relevant Agency policies including those on abortion, voluntary sterilization and human subjects research.

Justification to Congress: An Advice of Program Change reflecting the proposed increase is in process.

Recommendation: That you approve increased funding for Project 936-3005 by signing the attached authorization (Attachment 1).

Attachments:

1. Project Authorization
2. Project Data Sheet
3. Project Paper (936-3005)
4. Budget Table

Clearances:

ST/POP, SWSinding	<u>[Signature]</u>	Date	<u>5/2/85</u>
S&T/PO, GEaton	<u>[Signature]</u>	Date	<u>7/2/85</u>
ST/HP, JESarn	<u>[Signature]</u>	Date	<u>6/15/85</u>
PPC/PDPR, ARosenberg	<u>[Signature]</u>	Date	<u>6/23/85</u>
GC/CP, HFry	<u>[Signature]</u>	Date	<u>6/19/85</u>

ST/POP/R:LJDorflinger:clb:5/30/85:x59686:1627Z