

PD-ABK-886  
94232



U.S. AGENCY FOR  
INTERNATIONAL  
DEVELOPMENT

AUG 23 1993

Dr. Paul J. Fonteyn  
Associate Vice President  
Research and Sponsored Programs  
San Francisco State University  
1600 Holloway Avenue  
San Francisco, CA 94132

Subject: Grant No. HRN-5600-G-00-3016-00  
Assessment of PRC Predictive Test for Relapse in  
American Leishmaniasis

Dear Dr. Fonteyn:

Pursuant to the Authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development (hereinafter referred to as "A.I.D." or "Grantor") hereby grants to San Francisco State University (hereinafter referred to as "Grantee" or "University") the sum of \$149,900 to provide support for a research program entitled "Assessment of PCR Predictive Test for Relapse in American Leishmaniasis" as described in the Schedule of this Grant Attachment 1; the "Program Description" in Attachment 2; and the Grantee's technical proposal, as amended, which is made a part of the Grant and incorporated herein by reference.

This grant is effective and obligation is made as of the date of this letter and shall apply to commitments made by the Grantee in furtherance of program objectives during the period beginning September 1, 1993 and ending August 31 1995.

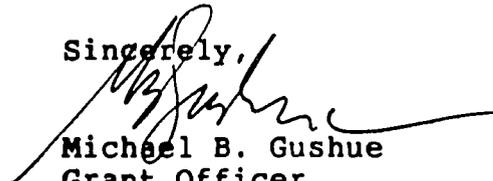
This grant is made to the Grantee on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment 3 entitled "Standard Provisions," which have been agreed to by your organization.

Please sign all copies of this letter to acknowledge your receipt of this Grant. Keep one copy for your files and return the original and all remaining copies to this office.

2 |

A.I.D. is pleased to issue this grant to the University and to support research in this field.

Sincerely,



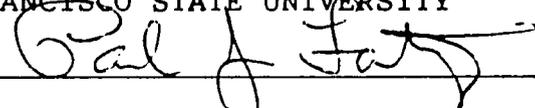
Michael B. Gushue  
Grant Officer  
Division A, HRN Branch  
Office of Procurement

Attachments:

1. Schedule
2. Program Description
3. Standard Provisions

ACKNOWLEDGED:

SAN FRANCISCO STATE UNIVERSITY

BY: 

TYPED NAME: PAUL J. FONTEYN  
ASSOCIATE VICE PRESIDENT

TITLE: RESEARCH AND SPONSORED PROGRAMS

DATE: SEPTEMBER 13, 1993

FISCAL DATA

PIO/T NO. : 3692436, 3 692436 A1  
3692437,  
Appropriation Number 72-1131021.1  
Budget Plan Code(s): : DDVA-93-16950-CG11  
DDVA-93-16950-KG11  
Allotment Number: 341-36-099-04-20-31  
Project Number 936-5600  
Total Estimated Amount: \$149,900  
Total Obligated Amount: \$149,900  
Obligated Amount by PIO/T:  
3692436 A1 \$74,900  
3692437 \$45,000  
3692436 \$30,000  
Project Office: R&D/R  
Voucher Paying Office: FM/CMPD/DCB  
Proposal Number: 10.211  
TIN: 94-6001347D8

**ATTACHMENT 1**

**SCHEDULE**

**A. Purpose of Grant**

The purpose of this Grant is to provide support for the San Francisco State University proposal entitled "Assessment of PCR Predictive Test for Relapse in American Leishmaniasis (10.211)" which is hereby incorporated by reference. This proposal was revised on March, 31 1993. In the event of conflict, the revised proposal takes precedence over the original.

**B. Period of Grant**

Funds obligated hereunder are available for program expenditures during the period beginning September 1, 1993 and ending August 31, 1995

**C. Amount of Grant and Payment**

1. A.I.D. hereby obligates the amount of \$149,900 for the purposes of this grant.

2. Payment shall be made to the Grantee in accordance with procedure set forth in the Standard Provision of this grant entitled "Payment - Letter of Credit."

3. All financial reports required by this provision shall be identified as PSTC Proposal No. 10.211 and be submitted to:

Agency for International Development  
FM/CMPD - Room 700, SA-2  
Washington, D.C. 20523 - 0209

**D. Grant Budget**

The following Budget for this Grant includes local cost items. Refer to the Standard Provision entitled "Local Cost Financing." Revisions to this budget shall be made in accordance with the Standard Provision of this grant entitled "Revision of Grant Budget."

(see next page)

**Budget (in USD):**

	Amount
Salaries	\$56,224
Equipment	14,856
Materials/Supplies	25,000
Local Travel/Patient	8,500
Training/Consultation:	
Dr. Orrego/Lima	4,000
Trainees/San Fran.	12,000
Administrative Costs:	
UPCH	13,000
Grantee	10,000
Other Direct Costs	6,320
	<hr/>
Total	\$149,900

Budget includes estimate for collaborating institution, Instituto de Medicina Tropical, Universidad Peruana

The Grantee shall be paid for administrative costs in accordance with Section I, "Indirect Cost Rates," below. The subgrantee shall be paid for administrative costs as agreed between the Grantee and the Subgrantee.

Within the total budget of the Grant, the Grantee may adjust the line items as reasonably necessary for the performance of the grant program.

**E. Participants**

## 1. Project Officer:

Caryn Miller  
R&D/H  
Room 1254, SA-18  
Agency for International Development  
Washington, D.C. 20523-1817

## 2. Principal Investigator:

Dr. Jorge Arevalo  
Instituto de Medicina Tropical "Alexander von Humboldt"  
Universidad Peruana Cayetano Heredia  
Lima 100, PERU

## 3. Collaborating Investigator:

Dr. Christian Orrego  
Genetics Laboratory  
Department of Biology  
San Francisco State University  
1600 Holloway Avenue  
San Francisco 94132

5

## F. Reporting and Evaluation

### 1. Technical Reports

Reports must be sufficiently detailed to substantiate the findings and to permit a scientific evaluation of the research. Overseas collaborators shall be given fair credit for their participation in the research and a chance to review and comment on the Final Report before it is submitted. The principal investigator will share a draft of the Final Report with the A.I.D. Project Officer for comments prior to the formal submission. Publication of results in scientific journals is encouraged. Additional guidance on report preparation is given in the "Interim Guidelines on Performance Report Preparation for PSTC and CDR Projects," available from AID/R&D/R.

- a. **Performance Reports:** Performance reports are required every six months. The principal investigator will submit reports stating what has been accomplished to date and detailing project management issues. A Financial Status Report will be attached to each report. Reports are due within sixty (60) days after the end of each six-month period. Four copies of each report are to be submitted to the Office of Research, Room 320 SA-18, Washington, D.C. 20523-1818; one copy to the Project Officer; one copy to the A.I.D. Mission (Lima, Peru); one copy to Center for Development Information and Evaluation (CDIE), Room 215C, SA-18, Washington, D.C. 20523-1802; and two copies to the National Academy of Sciences, BOSTID, 2101 Constitution Avenue, N.W., Washington, D.C. 20418.
- b. **Final Performance Report:** Within sixty (60) days after the termination of the Grant, the principal investigator will submit four copies of the Final Performance Report to the Office of Research, A.I.D., Room 320 SA-18, Washington, D.C. 20523-1818; one copy to the Project Officer; one copy to the Mission Lima, Peru; one copy to The Center for Development Information and Evaluation (CDIE), Room 215C, SA-18, Washington, D.C. 20523; and two copies to the National Academy of Sciences, BOSTID, 21 Constituion Avenue, N.W., Washington, D.C. 20418.

2. The Financial Status Report(SF-269) is required every three months as an attachment to the performance report and must be sent to the following Voucher Paying Office:

FM/CMP/DC  
Room 700 SA-2  
Agency for International Development  
Washington, D.C. 20523-0209

G. Special Provisions

1. Compliance with Federal Guidelines and Regulatory Procedures and PROTOCOLS

- a. The recipient will implement this research activity in accordance with all relevant guidelines for U.S. Government funded research such as:
- (1) The National Institutes of Health (NIH) guidelines for the ethical treatment of human subjects;
  - (2) Guidelines for the handling of radioactive materials;
  - (3) NIH and USDA guidelines for the handling of pathogenic microorganisms;
  - (4) USDA-APHIS procedures for animal and plant health inspection;
  - (5) The National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules;
  - (6) Procedures issued by the USDA, EPA, or other appropriate Federal agency, regarding testing of genetically engineered organisms;
  - (7) State Department's and A.I.D.'s environmental procedures; and
  - (8) Such other Federal guidelines and procedures as may apply during the course of research.
- b. All existing comparable guidelines of the host country in which the research is actually located must be followed also.

c. Reports submitted under this activity to A.I.D. will address the cited regulatory issues. All modifications of protocols affecting these regulatory concerns must be reported. The investigators are responsible for reporting any difficulties encountered in implementing these protocols.

2. Laboratory Safety and Hazard Containment: Research will be conducted following the protocols in this grant which insure the safety of persons involved in the research. Notwithstanding, the research must be conducted following procedures issued by the U.S. Government and those issued by the government of the host country for the containment of these hazards.

If the protocols involving laboratory safety and hazard containment are revised, they must be re-reviewed by the investigator's institutional review committee(s) that approved the original protocol, and the Project Officer and Office of Research must be informed in writing before the revised protocols are used. The revised procedures must be consonant with the guidelines of the country in which the laboratory is located and of the United States. Copies of the approval of the revised protocols by the investigator's institutional review committee(s) should also be provided the Project Officer and the Office of Research.

Similarly, the research will be conducted in the facilities described in Attachment 3. If the research is moved to new facilities, or the facilities are modified in such a way to affect safety or hazard containment, a description of the new facilities must be provided to the Project Officer and to the Office of Research before the research is affected. Any applicable institutional reviews of the facilities must be repeated, and the re-certification must be provided to the Project Officer and the Office of Research.

3. Humane Treatment of Experimental Animals:

a. Principles for the Treatment of Vertebrates: The grantee will adhere to the following principles for the utilization, care and transportation of vertebrate animals used in testing, research and training. For guidance throughout these principles, reference is made to the **Guide for the Care and Use of Laboratory Animals** prepared by the Institute of Laboratory Animal Resources, National Research Council.

- (1) Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- (2) The animals selected for a procedure should be an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation and in vitro biological systems should be considered.
- (3) Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in human beings may cause pain and distress in other animals.
- (4) Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- 5 Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure, or, if appropriate, during the procedure.
- (6) The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- (7) Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

- (8) Where exceptions are required in relation to the provisions of these principles, the decisions should not rest with the investigators directly concerned, but should be made, with due regard to U.S. and host country regulations, by an appropriate review group such as an institutional animal research committee. Such exception should not be made solely for the purpose of teaching or demonstration.
- b. Applicable Regulations: The transportation, care and use of animals should be in accordance with the U.S. Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable U.S. Federal laws, guidelines, and policies. Notwithstanding, the research must be conducted following procedures issued by the government of the host country for the humane treatment of experimental animals.
- c. Compliance with Reviewed Protocols: Research will be conducted following the protocols described in Attachment 3 (which is the original proposal or subsequent amendments, or letter from the Principal Investigator), which insure the humane treatment of experimental animals.
- d. Revision of Protocols: If any protocol involving the experimental animals is revised, it must be re-reviewed by the investigator's institutional review committee(s) that approved the original protocol, and the Project Officer and the Office of Research must be informed in writing before the revised protocol(s) is used. The revised procedures must be consonant with the guidelines of the country in which the animals are affected, and of the United States. Copies of the approval of the revised protocols by the investigator's institutional review committees should also be provided the Project Officer and the Office of Research.
- e. Facilities for Animals: The animals will be maintained in the facilities described. (which is the original proposal, subsequent amendments, or letter from the Principal Investigator). Notwithstanding, the animals must be provided facilities satisfying the requirements specified by the U.S. Government and those issued by the government of the host country for the humane treatment of experimental animals. If the animals are

moved to new facilities or the facilities are modified in such a way to affect the animals, a description of the new facilities must be provided to the Project Officer and to the Office of Research before the change is effected. Any applicable institutional reviews of the facilities must be repeated, and the re-certification should be provided to the Project Officer and the Office of the Science Advisor.

4. Human Subjects: Research will be conducted following the protocols described in (which is the original proposal or subsequent amendments or letter from the Principal Investigator), which insures the well-being and informed consent of human subjects. It will also be conducted in accord with the applicable procedures issued by the U.S. Government to insure ethical treatment of human subjects, and by those issued by the government of the host country in which the human subjects are to be involved.

If the protocol(s) involving human subjects is revised, it must be re-reviewed by the investigator's institutional ethical review committee, and the Project Officer and Office of Research must be informed in writing before the revised protocol(s) is used. The revised procedures must be consonant with the guidelines of the host country and of the United States. If the patient's informed consent form is revised, a copy of the new form must be submitted to both the Project Officer and the Office of Research. A copy of the approval of the revised form by the investigator's institutional ethical review committee must also be provided to the Project Officer and the Office of Research.

In addition and prior to commencement of any experimentation involving human subjects, the Grantee shall make a judgment and communicate the same to A.I.D. as to whether the regulations, procedures or facilities of the country in question are adequate to ensure the safety and free and informed consent of the human subjects. In the event such judgment is that they are not, the Grantee and A.I.D. will consult and agree on the protocol to be applied to insure the safety and free, informed consent of the subjects.

5. International Shipment of Organisms, Biologicals, or Controlled Materials or Equipment: Procedures for the international shipment of these materials must be in

agreement with those approved in the permits cited in (which is the original proposal or subsequent amendments or letter from the Principal Investigator). Notwithstanding, such shipments must be in compliance with International Import/Export Regulations for all countries to and from which regulated items are shipped. If the shipment procedures are varied from those specified for permits, permits for the revised procedures must be provided to A.I.D., Office of Research before shipping commences.

6. Intellectual Property Rights: Intellectual property rights stemming from the activities supported under this grant will be apportioned as described in Attachment 3 (which is the original proposal or subsequent amendments or letter from the Principal Investigator). If the participants choose to modify that apportionment, the revised apportionment must be submitted to the A.I.D. Project Officer for approval before it takes effect. Notwithstanding the intellectual property rights clauses provided in the following standard provisions apply.

#### H. Title to Property and Approval:

Title to property acquired hereunder shall vest in the Grantee, subject to the requirements of the Standard Provision of this Grant entitled "Title To and Use of Property (Grantee Title)" regarding use, accountability, and disposition of such property. Approval is given for the Grantee to purchase nonexpendable property as follows two thermocycles.

#### I. Indirect Cost Rates:

1. Pursuant to the Standard Provision of this Grant entitled "Negotiated Indirect Cost Rates - Predetermined," the Grantee shall be paid at the predetermined rate established with the cognizant U.S. Government audit agency, for each accounting period.

Predetermined Rate: 41.9% through 06/30/94  
Organized Research On-Campus

Base: Modified Total Direct Costs

12

**J. Standard Provisions;**

The Standard Provisions set forth as Attachment 3 of this Grant consist of the following Standard Provisions denoted by an "X" which are attached hereto and made a part of this Grant:

1. Mandatory Standard Provisions For U.S., Nongovernmental Grantees

- ( X ) Allowable Costs (November 1985)
- ( X ) Accounting, Audit, and Records (August 1992)
- ( X ) Refunds (September 1990)
- ( X ) Revision of Grant Budget (November 1985)
- ( X ) Termination and Suspension (August 1992)
- ( X ) Disputes (August 1992)
- ( X ) Ineligible Countries (May 1986)
- ( X ) Debarment, Suspension, and Other Responsibility Matters (August 1992)
- ( X ) Nondiscrimination (May 1986)
- ( X ) U.S. Officials Not to Benefit (November 1985)
- ( X ) Nonliability (November 1985)
- ( X ) Amendment (November 1985)
- ( X ) Notices (November 1985)
- ( X ) Metric System of Measurement (August 1992)

2. Additional Standard Provisions For U.S., Nongovernmental Grantees

- ( X ) OMB Approval Under the Paperwork Reduction Act (August 1992)
- ( X ) Payment - Letter of Credit (August 1992)
- ( ) Payment - Periodic Advance (January 1988)
- ( ) Payment - Cost Reimbursement (August 1992)
- ( X ) Air Travel and Transportation (August 1992)
- ( X ) Ocean Shipment of Goods (August 1992)
- ( X ) Procurement of Goods and Services (November 1985)
- ( X ) AID Eligibility Rules for Goods and Services (June 1993)
- ( X ) Subagreements (August 1992)
- ( X ) Local Cost Financing (June 1993)
- ( X ) Patent Rights (August 1992)
- ( X ) Publications (August 1992)
- ( X ) Negotiated Indirect Cost Rates - Predetermined (August 1992)
- ( ) Negotiated Indirect Cost Rates - Provisional (Nonprofits) (August 1992)
- ( ) Negotiated Indirect Cost Rates - Provisional (For-Profits) (August 1992)

- ( X ) Regulations Governing Employees (August 1992)
- ( X ) Participant Training (August 1992)
- ( ) Voluntary Population Planning (June 1993)
- ( X ) Protection of the Individual as a Research Subject (August 1992)
- ( X ) Care of Laboratory Animals (November 1985)
- ( X ) Title To and Use of Property (Grantee Title) (November 1985)
- ( ) Title To and Care of Property (U.S. Government Title) (November 1985)
- ( ) Title To and Care of Property (Cooperating Country Title) (November 1985)
- ( ) Cost Sharing (Matching) (August 1992)
- ( X ) Use of Pouch Facilities (August 1992)
- ( X ) Conversion of United States Dollars to Local Currency (November 1985)
- ( X ) Public Notices (August 1992)
- ( X ) Rights in Data (August 1992)

(end of Schedule)

PROGRAM DESCRIPTION

Title: Assessment to PCR Predictive Test for Relapse in  
American Leishmaniasis

SPECIFIC OBJECTIVE 1:

To link the research work plan described in this proposal to ongoing epidemiological studies on Leishmaniasis being carried out by members of the IMTAvH in endemic areas of the Amazonian jungle.

The IMTAvH is conducting clinical and epidemiological studies in the South Eastern part of the country which includes three Departamentos: Apurimac, Cusco and Madre de Dios (see Appendix 5). The field work operations center is in the city of Cusco where we have established a working network that involves local authorities of the Ministry of Health, the Instituto Peruano de Seguridad Social (Peruvian Social Security Institution), the University of San Antonio de Abad of Cusco, non governmental organizations and the local communities. This infrastructure has allowed a rational use of human and material resources to recruit patients with Leishmaniasis and for their follow-up with reduced number of lost cases.

Two studies on chemotherapy are being carried out in Cusco: "Study of the efficacy of Pentostam alone and in combination with Allopurinol in the treatment of mucocutaneous Leishmaniasis" (TDR/WHO Project Nº L30/181/28, Jan. 1989-Dec. 1990, with a possible 1 year extension period) and "The influence of salt loading on the renal response to Amphotericin B in man" (Squibb Laboratories, 2 years project ending Dec. 1989). A third project, already approved by Squibb laboratories for funding, on "Amphotericin B lipid complex in treatment of patients with mucocutaneous Leishmaniasis" (Protocol 31, 916-03), will continue the latter.

The present proposed project will use the infrastructure, local manpower, clinical protocols and the biopsies of patients already available in the

15

projects mentioned above. This is feasible because the experimental part of this proposal does not require modifications on the high standard management of patients and field work to be used in those other projects. Actually PCR will strengthen those protocols, specially if it is a reliable test for parasitological demonstration and a criterion of cure.

Patients to be studied will be recruited among those attending health post services and main hospitals in the city of Cusco. Furthermore, active recruiting will be carried out during planned visits of our research team to the rural communities. A trained physician attached to the projects mentioned above will interview and examine patients with Leishmaniasis. Laboratory procedures to demonstrate the presence of the parasite and the intradermal skin test of Montenegro will be performed. Voluntary candidates will be selected using the criteria mentioned in Section 2.1, below. Biopsies will be obtained by trained personnel. Improved standardized clinical records will be stored in a Database. Ethical considerations have been fully taken into account and are described in Appendix 7.

Pentavalent antimonials (20 mg Sb<sup>V</sup>/Kg of weight/day during 30 days) will be administered in a controlled manner by trained physicians collaborating with this project. This is the therapeutic scheme recommended by the WHO. Patients will be followed-up for a one year period after reaching the clinical criteria of cure as defined in Section 2.1. The patients participating in the therapeutic protocols in Cusco will be hospitalized for a one month period. The same trained physician that enrolled them in the scheme will perform the follow-up examinations and note the clinical criteria of cure. Appointments will be arranged for months 2, 3, 6 and 12 after the onset of treatment.

Very small biopsy samples will be obtained from patients for diagnostic purposes according to Section 2.2. Biopsy samples will be taken before and at the end of treatment (day 30). Part of the biopsy will be subjected to PCR and the remaining will be stored at - 70°C. If biopsy sample results PCR positive, the test will be repeated once more with the cryopreserved sample. Only if positive result is confirmed, a second biopsy will be obtained 30 days later (day 60). This will be performed if the patients do not have completely healed lesions. If on the other hand, they have healed scarred lesions, four aspirates from the lesion will be taken for PCR testing. It is better not to take biopsies from scars as they are fibrotic. Our preliminary results suggest that our PCR test works well with aspirated samples (Appendix 4). This biopsy (day 60) should rule out the possibility that DNA detected in day 30 may be due to the presence of remaining Leishmania DNA in spite of the fact that all parasites could have been killed by the chemotherapy. We have the reasonable expectation that one month after the end of the treatment, host mechanisms should have removed any Leishmania DNA traces.

According to the protocols of the chemotherapy trial projects to which this proposed project will be linked, during the one year follow-up period, those patients who relapsed will be subjected to laboratory procedures to detect the presence of Leishmanias in the reactivated lesion. As routine they will be biopsied again. A fragment of these biopsies will be used for the PCR test, another part for attempting the isolation of parasites to pursue standard diagnosis and characterization studies, and the remaining will be cryopreserved for future analysis.

The other endemic area of Leishmaniasis that will be studied is Yurimaguas, in the Provincia of Alto Amazonas, in the Departamento of Loreto (see Appendix 5). We will use existing infrastructure through a project on Hansen's disease carried out by the IMTAyH and the Ministry of Health. This project is funded by the Ped Parnet Foundation from Denmark. Dr. Eduardo Falconi directs this effort and has also carried out clinical studies on the high prevalence of Leishmaniasis in the area. The protocols to be performed are the same as those already described for Cusco.

To achieve the objectives of the proposal we will provide Alto Amazonas health personnel (Physician, nurses and paramedical workers) with a one month intensive training period at the IMTAyH. They will be trained on biopsy sampling and parasite isolation techniques in culture. At their return they will start recruitment of patients and to obtain samples for the study. Periodic visits from tropicalists and investigators from the IMTAyH and the UNAP will continue strengthening of the capabilities of the health workers in that field work station.

In both Cusco and Yurimaguas, primary isolates will be obtained. These will be sent together with the biopsies to the IMTAyH in Lima. We have an ongoing system for proper transportation of samples from these areas to Lima via regular airways.

An ELISA test measuring IgG response against Leishmania will be carried out with sera obtained from patients admitted in this study. Measurement of IgG titers before treatment, at different intervals during it and also through the follow-up period after it, will be performed. This study will allow us to compare the PCR test with a serological indirect one, both as criterion of cure and as predictive test for relapse.

#### SPECIFIC OBJECTIVE 2:

To establish if the absence of Leishmania DNA in human biopsies, as determined by the PCR, after treatment of MCL patients is a reliable criterion of cure. Conversely to assess if its presence can be correlated with a likelihood of subsequent disease relapse.

The results obtained from the use of the PCR test as a criterion of cure will be contrasted on the same patients with those using the following clinical and parasitological definitions (these measurements are part of the studies on chemotherapeutic protocols):

**Clinical cure.-** complete healing of the lesion (epithelialization) with disappearance of edema, induration and/or other signs of inflammation.

**Definitive cure.-** non recurrence of the lesion(s) in the site of the original lesion after one year of post-therapy follow-up.

**Therapeutic failure.-** clinical nonhealing of the lesion and persistence of parasites by smear and/or culture and/or hamster inoculation by three months post therapy

**Parasitological cure.-** absence of parasites as determined by a negative smear and/or negative culture and/or negative inoculation in the hamster

and/or PCR negative.

Relapse.- those lesions from patients who present reactivation of the healed mucosal tissue, without concomitant apparition of new cutaneous lesions in other regions of the body. This restriction is made in order to avoid misinterpretations due to possible, although very improbable, reinfection or due to lesions with different etiology.

## 2.1. STUDY POPULATION

The study for this specific objective will include patients if they fulfil the following criteria:

Criteria of Inclusion:

- 1) Active mucocutaneous lesion.
- 2) Parasitological demonstration of parasites in the lesion at least by PCR.
- 3) To be enrolled in the controlled chemotherapeutic protocol with pentavalent antimonials described above. This implies the willingness to participate in the project during a one year period and the signature of an informed consent (appendix B).

Criteria of exclusion:

- 1) Patients with subjacent systemic disease.
- 2) Severe adverse side effects to the drugs to be used in the therapeutic schemes.
- 3) Request for removal from the study.

## 2.2. PROCESSING OF THE BIOPSY SAMPLES

Biopsy samples will be obtained by an otorrhinolaringologist from anesthetized mucous tissue at different periods of time as mentioned above, using sterile forceps according to IMTAVH routinary protocols. All material to be used will be either new or treated with Sodium Hypochlorite (1.5%) to avoid false positives in the PCR protocol. The biopsy will be divided in half. One half will be stored at  $-20^{\circ}\text{C}$  to be subjected to PCR at the IMTAVH. The other half of the biopsy, to be used for culture isolation will be incubated for 3 hours in saline solution with antibiotics (180 ug/ml Penicillin, 300 ug/ml Streptomycin and 150 ug/ml 5-Fluorocytosine). It will be homogenized and the crude supernatant will be placed in a biphasic medium containing 10% rabbit blood and at the same time it will be inoculated in a golden hamster (Mesocricetus auratus).

Primary isolation and growth of Leishmanias will be attempted in the endemic areas, where we have laboratory facilities at the local health centers. When cultures became available, four replica tubes will be sent to the IMTAVH, where two of them will be kept for cryopreservation and the other two will be sent to the Biochemistry Department of the UNAP for their characterization by zymodemes and schyzodemer (see below). Cryopreserved samples will be stored at  $-70^{\circ}\text{C}$  for future retrospective studies.

#### 2.4. POLYMERASE CHAIN REACTION DETECTION METHOD

Biopsies will be homogenized in a glass tissue grinder with 200 - 300 ul of lysis buffer (10 mM Tris.HCl pH 7.5, 100 mM NaCl, 5 mM EDTA) and incubated at 65°C for at least two hours. An aliquot of 2 ul from a biopsy crude homogenate is necessary for diagnosis of Leishmaniasis by PCR for patients without treatment. In the case of patients that have finished their treatment and who will participate in this protocol, 4 aliquots of 2 ul each will be subjected to PCR. We assumed that the number of amastigotes in healed patients, if present, will be scarce. Increasing the number of PCR tests per patient will improve the chances to detect Leishmania parasites and thus to detect potential cases of relapse.

PCR conditions will be those reported by us (16). Briefly 2 ul from the homogenate will be incubated in presence of 20 ul of a mixture solution containing PCR buffer (0.671 M Tris.HCl pH 8.8, 0.167 M  $(\text{NH}_4)_2\text{SO}_4$ , 0.1M 2-mercaptoethanol, 0.02M  $\text{MgCl}_2$ ), 250 uM of the four dNTPs, 1 uM of each flanking primer and 2.5 units of Taq polymerase. An overlay of 30 uls of mineral oil will be added to avoid evaporation during the denaturing-annealing cycles. At least twenty eight denaturation -annealing- Taq polymerase extension cycles will be performed unless otherwise stated. The temperatures for denaturation, annealing and extension will be 94°C, 54°C and 72°C respectively. The entire procedure takes less than 2 hours and we process a large number of samples.

The results of the PCR amplification will be observed by ethidium bromide staining after running 3 ul of the samples in 4% NuSieve agarose (FMC). OX 174- Hae III DNA fragments will be used as size markers. The rest of the sample will be stored at -70°C for later analysis of the amplified product if necessary.

According to our hypothesis we expect to find that most PCR positive patients after completed the treatment will eventually relapse. It is possible however that we might find that some patients who remain PCR positive after treatment will not relapse during the follow-up period. In this case we cannot discard that such patients could relapse later on, but it might be also possible that parasites in such patients remain in a quiescent stage, as if an equilibrium between parasite and host's defense mechanisms would have been achieved. In fact there are evidences that suggest that not all infected people develop the clinical disease (33, 34).

To explore the possibility that relapse may be related to the parasite load after the end of the treatment we will also carry out gene dosage experiments by PCR co-amplification. This approach consists in the amplification of two sequences in the same vial, one which number of copies is known beforehand and the other which is the patient's sample. At the end of the amplification cycles we can apply the following equation:

$$\log(N_1/N_2) = n \log(f_1/f_2) + \log(s_1/s_2)$$

where  $N_1$  = number of copies after  $n$  amplification cycles  
 $s_1$  = number of copies before the in vitro amplification  
 $f_1$  = efficiency of PCR ( $1 < f_1 < 2$ )

From this equation and after estimating the number of amplified copies

6

obtained of my standard reference DNA we could calculate the number of parasites present in the biopsy.

## 2.5 STATISTICAL ANALYSIS

A main objective of this proposal is to determine if PCR could be a reliable test to predict relapse. In order to do that, we need to estimate:

- (a) The percentage of persons having relapsed who are correctly predicted by PCR (sensitivity).
- (b) The percentage of persons having not relapsed (cured) who are correctly identified as such by PCR (specificity).

As these two are proportions, the sample size can be computed on the basis of an expected value of 80% (either sensitivity or specificity), so that for a 95% confidence interval of  $\pm 20\%$ , the sample size needed is 50 (after an allowance for drop-outs). Given that around 30% of MCL patients are expected to relapse during the one year follow-up period, we need a universe of 150 such patients.

Statistical analysis will comprise:

1) Relapse rates estimated as number of relapses per patient-week of follow-up (from the clinically cured stage until the last visit (expected 12 months) or start of relapse.

This will be computed by dividing the actual number of relapses observed in each PCR category by the sum of individual follow-up times (up to the end of follow-up or onset of relapse or drop-out time) in the corresponding PCR category. These proportions will have a 95% confidence interval using the Freeman-Tukey approximation (see Table I):

TABLE I

Patients included in this study according PCR categories

PCR category	Number of relapses	Proportion of relapses	Total time of follow-up in patient-weeks	Relapse rate
+30d/+60d	$N_1$	$R_1/N_1$	$T_1$	$R_1/T_1$
+30d/-60d	$N_2$	$R_2/N_2$	$T_2$	$R_2/T_2$
-30d/*	$N_3$	$R_3/N_3$	$T_3$	$R_3/T_3$

where d= days after the onset of treatment, when the biopsy for PCR will be obtained; += PCR positive result; -= PCR negative result; \*= patients cannot be biopsied; N= number of patients in each category; R= number of patients who relapse in each category; T= time of follow-up in patients-week.

It would also be very interesting to observe if there is a correlation between the date of relapse and the different PCR categories.

20

expected size amplification products will be further studied as a tool to characterize parasite's heterogeneity with a large number of sylvatic isolates cryopreserved in our bank of strains. We will select strains obtained from cured and non cured patients and then analyze amplification products of all these strains in terms of size heterogeneity, RFLP with 4bp restriction enzymes, hybridization with Allelic single oligonucleotide probes (ASOs) and direct DNA sequencing of PCR amplification products (39).

#### Characterization via PCR using mitochondrial DNA sequences

We will also study mitochondrial rRNA genes, because these evolve more rapidly than nuclear DNA sequences. We will study the contiguous mitochondrial genes encoding 9S rRNA and 12S rRNA and the intergenic region between them. The DNA sequence of this region of Crithidia fasciculata, Leptomonas sp., Trypanosoma cruzi, Trypanosoma brucei and Leishmania tarentolae has been completely obtained and contain sequences of extensive homology (40). Based on these data we will synthesize oligomers to be tested as extension primers specific for these three regions of the maxicircle. We expect that intergenic regions show higher divergency than ribosomal genes and can potentially be used to characterize Leishmania isolates obtained from relapsed and non relapsed MCL patients.

Another approach using the mitochondrial DNA of Leishmanias will be to amplify a major part of the variable section of the minicircle based on an apparently "universal" minicircle sequence in all kinetoplast species. The 12-mer GGGTGGGTGATAA has been reported in L. tarentolae, L. brucei, L. equiperdum, L. cruzi and C. fasciculata. During the studies that conducted to the detection of the 65 bp consensus minicircle kinetoplast DNA sequence we have detected the presence at least once of the 12-mer in L. braziliensis (unpublished results).

As illustrated in Figure 1 (Appendix 10) we expect that one or the other of the primers directed to the universal "dodecamer" site in an appropriate combination with the primers already available for the amplification of the L. braziliensis complex (primers MP-1L and MP-3H) will permit amplification of the variable region of the minicircle. Should there be more than one dodecamer sequence present this will be revealed by more than one amplification fragment. Though the primers directed to the dodecamer site will initially have only six bases for annealing, such length is often enough for successful priming in the PCR (Incher and White, Evolutionary Analysis via PCR, 1989, in press).

Amplification products will be analyzed with similar approaches that to nuclear DNA sequences. After selecting DNA sequences with potential use to distinguish between strains predominantly associated with treatment failure we will use them to study biopsied material from patients to be comprised in this follow-up study.

On the other hand, information to be obtained will be correlated with other clinical and biological parameters as we have excellent clinical records, sera from patients and biochemical characterization of isolates, which will allow to carry out a retrospective study on them.

8

B) Sensitivity and Specificity of PCR to predict relapse.

Sensitivity will be computed by dividing the actual number of relapses that are PCR positive by the total number of relapses observed. Specificity will be computed by dividing the actual number of PCR negative individuals who have not relapsed by the total number of non relapsed individuals. The proportions to be obtained will have a 95% confidence interval using the Freeman-Tukey approximation (see Table II):

TABLE II

Sensitivity and Specificity of PCR to predict relapse.

	Relapsed	Non-relapsed
PCR +	a	b
PCR -	c	d
Sensitivity= $a/(a+c)$ ; Specificity= $d/(b+d)$		

SPECIFIC OBJECTIVE 3:

To search for genomic markers that can distinguish Leishmania parasites that are predominant in MCL patients that relapse.

In this part of the project we will attempt a qualitative approach, of searching for differences in the genetic make-up of the parasites, to the problem of disease relapse as opposed to the quantitative approach, of presence of parasites in the lesion after treatment, followed in Section 2.

The phenomenon of chemotherapeutic success or failure in patients suffering Leishmaniasis could reflect differences between Leishmania strains. Such heterogeneity may also be related to the spectrum of clinical forms found among MCL patients. To address the question of Leishmania heterogeneity as possible cause of treatment failure we will use the amplification of specific DNA sequences via PCR. This technique does not depend on the isolation and growth of parasites which is needed for conventional characterization procedures. Therefore PCR should avoid possible bias imposed by growing conditions and also it would allow the study of a significantly higher number of Leishmania strains of patients that relapse, through the study of specific sequences. In this part of the project we will search for DNA sequences that when used as extension primers could detect differences between those parasites that are predominantly found in patients who relapsed after controlled treatment. Results using PCR will be compared with the more conventional characterization procedures zymodeme and schyzodeme analysis.

### 3.1. PATIENT POPULATION

This part of the study will include characterization of parasites present in, or isolated from, lesions of patients with MCL who fulfil the following criteria:

- 1) Active mucocutaneous lesion without previous specific treatment.
- 2) Parasitological demonstration of parasites in the lesion at least by PCR.
- 3) To be enrolled in the controlled chemotherapeutic protocol with pentavalent antimonials described above. This implies the willingness to participate in the project during a one year period and the signature of an informed consent (appendix B).

Criteria of exclusion:

- 1) Patients with subjacent systemic disease.
- 2) Severe adverse side effects to the drugs to be used in the therapeutic schemes.
- 3) Request for removal from the study.

### 3.2. CHARACTERIZATION OF *L. braziliensis* STRAINS VIA THE POLYMERASE CHAIN REACTION.

We will compare parasites from patients that relapsed with those from patients that cured by the analysis of DNA sequences, both nuclear and mitochondrial, amplified by PCR. We will develop several extension primers specific for different DNA sequences. They will be used to amplify DNA of parasites present in the lesion before and after the treatment, if parasites persist. According to a main working hypothesis of this proposal most of the post treatment PCR positive lesions will relapse.

#### Characterization via PCR using nuclear DNA sequences

We will use the gene encoding for the gp63 major surface glycoprotein of the genus *Leishmania*, also referred to as the promastigote surface protease (35). This protein has been found in *Leishmanias* of the Old and New Worlds. The natural biological role of gp63 is unclear since besides its protease activity it is involved in the phagocytosis of the parasite by host macrophages via C3 receptors (36) It is also able to induce host protective immune response against *Leishmania mexicana* when presented in liposomes (37).

This part of the project will be carried out in collaboration with Dr. W. Robert Mc Master of the Department of Medical Genetics, from the University of British Columbia, Canada. He has already used PCR and primers based on the *L. major* gp63 sequence to directly clone that gene, from genomic DNA of a variety of Old World and New World *Leishmania* species (38, see Appendixes B,9). Using *L. major* extension primers we will clone and sequence gp63 of four different *Leishmania* strains from Cusco and Loreto that are stored in our cryobank, two cured and the other two non-cured. DNA sequences will be analyzed in a search for regions that show a high diversity but flanked by consensus DNA sequences that may work as extension primers. A similar approach was followed to design our minicircle extension primers for the diagnosis of human *Leishmaniasis* (16). Those extension primers that provide

### 3.3. CHARACTERIZATION OF *Leishmania braziliensis* STRAINS BY ZYMODEME AND SCHYZODEME ANALYSIS.

The main purpose of this part of the project is to correlate the results of characterization results via PCR with relatively more conventional techniques and also to evaluate the advantages that PCR may have over these techniques. They have been extensively used in our laboratory and by other research groups for the characterization of *Leishmania* strains and other trypanosomatids (22,24,25,26,41,42,43). We will transfer these methodologies to the Biochemistry Department of the UNAP. This research group lives and works in the endemic area of Loreto and will support field work studies at Yurimaguas.

We will train two young investigators from the UNAP here in the IMTA-VH during a three months period. At their return they will start the characterization of the isolates that will be sent from the IMTA-VH.

Thirteen isoenzymes will be used to characterize each isolate: ALAT, ASAT, GPI, G6PD, GPI, PGM, ICD, 6PDG, ME, PGM, ICD, MDH and MPI (the two latter discriminates between andean and sylvatic *Leishmanias*) (44,45). Kinetoplast DNA preparations will be obtained according Goncalves et al (26). Standard reference strains, LTB300 (*L. b. braziliensis*), LC53 (*L. b. braziliensis*), LC26 (*L. b. peruviana*) and M4147 (*L. b. guyanensis*) will be included in each electrophoretic run. Photographs of each pattern will be recorded and migration rates of the different isoenzymes will be drawn on millimeter paper. These data will be sent to Lima to be processed.

Schizodeme analysis will be performed with the four base pairs restriction enzymes MspI, Hae III, Mbo I and HincII. These restriction enzymes have been chosen based on our previous experience on the degree of complexity of the pattern. The first two enzymes generate a relatively simple restriction pattern as only few fragments were observed after electrophoresis in 6-10% gradient PAGE. The other two enzymes provide a pattern of intermediate complexity that can be analyzed without the use of a scanner (22). Lambda Hind III -0x174 HincII restriction fragments will be included as length size markers. Electrophoretic patterns of the problem samples plus the reference strains will be photographed, dried between two cellophane sheets and sent to Lima for final data processing.

**STANDARD PROVISIONS**

Note: Only those Standard Provisions indicated in 1J of the Schedule of this Grant apply to this Grant. The Standard Provisions are provided here in their full text.

See attached Standard Provisions dated September 29, 1992.

REVISED

SEPTEMBER 29, 1992

MANDATORY STANDARD PROVISIONS FOR  
U.S., NONGOVERNMENTAL GRANTEES<sup>1</sup>INDEX OF  
MANDATORY STANDARD PROVISIONS

- |                                   |   |
|-----------------------------------|---|
| 1. Allowable Costs                | 8. Debarment, Suspension, and other<br>Responsibility Matters |
| 2. Accounting, Audit, and Records | 9. Nondiscrimination  |
| 3. Refunds                        | 10. U.S. Officials Not to Benefit                             |
| 4. Revision of Grant Budget       | 11. Nonliability  |
| 5. Termination and Suspension     | 12. Amendment   |
| 6. Disputes                       | 13. Notices   |
| 7. Ineligible Countries           | 14. Metric System of Measurement                              |

\* 1. ALLOWABLE COSTS (NOVEMBER 1985)

The grantee shall be reimbursed for costs incurred in carrying out the purposes of this grant which are determined by the grant officer to be reasonable, allocable, and allowable in accordance with the terms of this grant, any negotiated advance understanding on particular cost items, and the applicable\* cost principles in effect on the date of this grant.

\* NOTE: For Educational Institutions use OMB Circular A-21; for all other non-profits use OMB Circular A-122; and for profit making firms use FAR 31.2. and AIDAR 731.2.

2. ACCOUNTING, AUDIT, AND RECORDS (AUGUST 1992)

(a) The grantee shall maintain books, records, documents, and other evidence in accordance with the grantee's usual accounting procedures to sufficiently substantiate charges to the grant. The grantee's financial management system shall provide for the following:

(1) Accurate, current, and complete disclosure for each AID-sponsored project or program in accordance with the reporting requirements of this grant. While AID requires reporting on an accrual basis, the grantee shall not be required to establish an accrual accounting system but shall develop such accrual data for its reports on the basis of an analysis of the documentation on hand.

<sup>1</sup>When these Standard Provisions are used for cooperative agreements, the following terms apply: "Grantee" means "Recipient," "Grant" means "Cooperative Agreement," and "AID Grant Officer" means "AID Agreement Officer."

\* REVISED

267

(2) Records that identify adequately the source and application of funds for AID-sponsored activities. These records shall contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, and income.

(3) Effective control over and accountability for all funds, property, and other assets. Grantee shall adequately safeguard all such assets and shall ensure that they are used solely for authorized purposes.

(4) Comparison of actual outlays with budget amounts for each grant. Financial information should be related to performance and unit-cost data whenever appropriate.

(5) Procedures to minimize the time elapsing between the transfer of funds from the U.S. Treasury and the disbursement by the recipient, whenever funds are advanced by the Federal Government.

(6) Procedures for determining the reasonableness, allowability, and allocability of costs in accordance with the provisions of the applicable Federal cost principles and the terms of the grant.

(7) Accounting records that are supported by documentation that at a minimum will identify, segregate, accumulate, and record all costs incurred under a grant and which fully disclose (i) the amount and disposition by the grantee of the proceeds of such assistance; (ii) the total cost of the project or undertaking in connection with which such assistance is given or used, (iii) the amount of that portion of the cost of the project or undertaking supplied by other sources, and (iv) such other records as will facilitate an effective audit.

\* (8) A systematic method to ensure timely and appropriate resolution of audit findings and recommendations.

(b) The grantee shall require subrecipients to adopt the standards in paragraph (a) above except that portion of subparagraph (a)(1) that would require specific financial reporting forms and frequencies in accordance with the payment provisions of this grant.

(c) If the grantee is a nonprofit institution, it shall conduct audits in accordance with the requirements of OMB Circular A-133, "Audits of Institutions of Higher Education and Other Nonprofit Institutions" and shall ensure that nonprofit subrecipients conduct audits and submit them to the grantee in accordance with the Circular.

(d) The grantee shall preserve and make available such records for examination and audit by AID and the Comptroller General of the United States, or their authorized representatives:

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\* (1) until the expiration of three years from the date of termination of the grant;

(2) for such longer period, if any, as is required to complete an audit to resolve all questions concerning expenditures unless written approval has been obtained from the grant officer to dispose of the records. AID follows generally accepted accounting practices in determining that there has been proper accounting and use of grant funds. The grantee agrees to make available any further information requested by AID with respect to any questions arising as a result of the audit; and

(3) If any litigation, claim, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved.

(e) The grantee shall insert paragraph (d) above in all subagreements.

3. REFUNDS (SEPTEMBER 1990) \*

(a) The grantee shall remit to AID all interest earned on funds provided by AID at least quarterly, except that interest amounts up to \$100 per year may be retained by the grantee for administrative expense.

(b) Funds obligated by AID but not disbursed to the grantee at the time the grant expires or is terminated shall revert to AID, except for such funds encumbered by the grantee by a legally binding transaction applicable to this grant. Any funds advanced to but not expended by the grantee and not encumbered by a legally binding transaction applicable to this grant at the time of expiration or termination of the grant shall be refunded to AID.

(c) AID reserves the right to require refund by the grantee of any amount which AID determines to have been expended for purposes not in accordance with the terms and conditions of this grant, including but not limited to costs which are not allowable in accordance with the applicable Federal cost principles or other terms and conditions of this grant. In the event that a final audit has not been performed prior to the closeout of this grant, AID retains the refund right until all claims which may result from the final audit have been resolved between AID and the grantee.

\* REVISED

287

4. REVISION OF GRANT BUDGET (NOVEMBER 1985)

(a) The approved grant budget is the financial expression of the grantee's program as approved during the grant award process.

(b) The grantee shall immediately request approval from the grant officer when there is reason to believe that within the next 30 calendar days a revision of the approved grant budget will be necessary for the following reasons:

(1) Changes in the scope or the objectives of the program and/or revisions in the funding allocated among program objectives.

(2) The need for additional funding.

(3) The grantee expects the amount of AID authorized funds to exceed its needs by more than \$5,000 or five percent of the AID award, whichever is greater.

(4) The grantee plans to transfer funds budgeted for indirect costs to absorb increases in direct costs or vice versa.

(5) The grantee intends to contract or subgrant any of the substantive programmatic work under this grant, and such contracts or subgrants were not included in the approved grant budget.

(6) The grantee plans to incur an expenditure which would require advance approval in accordance with the applicable Federal cost principles and was not included in the approved grant budget.

(7) The grantee plans to transfer funds allotted for training allowances to other categories of expense.

(c) When requesting approval for budget revisions, the grantee shall use the budget formats that were used in the application unless a letter request will suffice.

(d) Within 30 calendar days from the date of the receipt of the request for budget revisions, the grant officer shall review the request and notify the grantee whether the budget revisions have been approved. If the revisions are still under consideration at the end of 30 calendar days, the grant officer shall inform the grantee in writing of the date when the grantee may expect the decision. The grant officer shall obtain the project officer's clearance on all such requests prior to communication with the grantee.

(e) If the requested budget revision requires the obligation of additional funding, and if after notification pursuant to this standard provision, AID determines not to provide additional funds, the AID grant officer will, upon written request of the grantee, terminate this grant pursuant to the standard provision of this grant, entitled "Termination and Suspension."

(f) Except as required by other provisions of this grant specifically stated to be an exception from this provision, the Government shall not be obligated to reimburse the grantee for costs incurred in excess of the total amount obligated under the grant. The grantee shall not be obligated to continue performance under the grant (including actions under the "Termination and Suspension" provision) or otherwise to incur costs in excess of the amount obligated under the grant, unless and until the grant officer has notified the grantee in writing that such obligated amount has been increased and has specified in such notice the new obligated grant total amount.

5. TERMINATION AND SUSPENSION (AUGUST 1992)

\* (a) For Cause. The grant officer may terminate this grant for cause at any time, in whole or in part, upon written notice to the grantee, whenever it is determined that the grantee has failed to comply with the terms and conditions of the grant.

(b) For Convenience. This grant may be terminated for convenience at any time by either party, in whole or in part, if both parties agree that the continuation of the grant would not produce beneficial results commensurate with the further expenditure of funds. Both parties shall agree upon termination conditions, including the effective date and, in the case of partial terminations, the portion to be terminated. The agreement to terminate shall be set forth in a letter from the grant officer to the grantee.

(c) Suspension or Termination for Changed Circumstances. If at any time AID determines that continuation of all or part of the funding for a program should be suspended or terminated because such assistance would not be in the national interest of the United States or would be in violation of an applicable law, then AID may, following notice to the grantee, suspend or terminate this grant in whole or in part and prohibit the grantee from incurring additional obligations chargeable to this grant other than those costs specified in the notice of suspension during the period of suspension. If the situation causing the suspension continues for 60 days or more, then AID may terminate this grant on written notice to the grantee and cancel that portion of this grant which has not been disbursed or irrevocably committed to third parties.

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(d) Termination Procedures. Upon receipt of and in accordance with a termination notice as specified in either paragraph (a) or (b) above, the grantee shall take immediate action to minimize all expenditures and obligations financed by this grant and shall cancel such unliquidated obligations whenever possible. Except as provided below, no further reimbursement shall be made after the effective date of termination. The grantee shall within 30 calendar days after the effective date of such termination repay to the Government all unexpended AID funds which are not otherwise obligated by a legally binding transaction applicable to this grant. Should the funds paid by the Government to the grantee prior to the effective date of the termination of this grant be insufficient to cover the grantee's obligations in the legally binding transaction, the grantee may submit to the Government within 90 calendar days after the effective date of such termination a written claim covering such obligations. The grant officer shall determine the amount(s) to be paid by the Government to the grantee under such claim in accordance with the applicable cost principles.

6. DISPUTES (AUGUST 1992)

\* (a) Any dispute under this grant shall be decided by the AID grant officer. The grant officer shall furnish the grantee a written copy of the decision.

(b) Decisions of the AID grant officer shall be final unless, within 30 days of receipt of the decision of the grant officer, the grantee appeals the decision to AID's Deputy Associate Administrator for Finance and Administration. Any appeal made under this provision shall be in writing and addressed to the Deputy Associate Administrator for Finance and Administration, Agency for International Development, Washington, D.C. 20523. A copy of the appeal shall be concurrently furnished to the grant officer.

(c) In order to facilitate review on the record by the Deputy Associate Administrator for Finance and Administration, the grantee shall be given an opportunity to submit written evidence in support of its appeal. No hearing will be provided.

(d) A decision under this provision by the Deputy Associate Administrator for Finance and Administration shall be final. \*

7. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the AID grant officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

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\* B. DEBARMENT, SUSPENSION, AND RELATED MATTERS (AUGUST 1992)

(a) As a condition of receiving this grant, the grantee has submitted the certifications required by AID Regulation 8 (22 CFR Part 208) both for itself and any prospective lower tier participants identified up to the date of award of the grant. The grantee also agrees to secure required certifications from lower tier participants identified after the date of the award, to notify AID in the event of changed circumstances affecting the validity of its certifications, to require lower tier participants to notify the grantee in the event of changed circumstances affecting the validity of their certifications, and to otherwise comply with AID Regulation 8 in all respects.

(b) In addition to the above, the grantee agrees that, unless authorized by the grant officer, it will not knowingly enter into any subagreements or contracts under this grant with a person or entity included on the "Lists of Parties excluded from Federal Procurement or Nonprocurement Programs." The grantee further agrees to include the following provision in any subagreements or contracts entered into under this grant:

DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION (MARCH 1989)

The recipient/contractor certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

9. NONDISCRIMINATION (MAY 1986) \*

(This provision is applicable when work under the grant is performed in the U.S. or when employees are recruited in the U.S.)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity funded by this grant on the basis of race, color, national origin, age, handicap, or sex.

10. U.S. OFFICIALS NOT TO BENEFIT (NOVEMBER 1985)

No member of or delegate to the U.S. Congress or resident U.S. Commissioner shall be admitted to any share or part of this grant or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this grant if made with a corporation for its general benefit.

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11. NONLIABILITY (NOVEMBER 1985)

AID does not assume liability for any third party claims for damages arising out of this grant.

12. AMENDMENT (NOVEMBER 1985)

The grant may be amended by formal modifications to the basic grant document or by means of an exchange of letters between the grant officer and an appropriate official of the grantee.

13. NOTICES (NOVEMBER 1985)

Any notice given by AID or the grantee shall be sufficient only if in writing and delivered in person, mailed, or cabled as follows:

To the AID grant officer, at the address specified in the grant.

To grantee, at grantee's address shown in the grant or to such other address designated within the grant.

Notices shall be effective when delivered in accordance with this provision, or on the effective date of the notice, whichever is later.

\* 14. METRIC SYSTEM OF MEASUREMENT (AUGUST 1992)

Wherever measurements are required or authorized, they shall be made, computed, and recorded in metric system units of measurement, unless otherwise authorized by the grant officer in writing when it has found that such usage is impractical or is likely to cause U.S. firms to experience significant inefficiencies or the loss of markets. Where the metric system is not the predominant standard for a particular application, measurements may be expressed in both the metric and the traditional equivalent units, provided the metric units are listed first.

(END OF MANDATORY STANDARD PROVISIONS)

\* REVISED

OPTIONAL STANDARD PROVISIONS FOR  
U.S. NONGOVERNMENTAL GRANTEES

The following standard provisions are required to be used when applicable. Applicability statements are contained in the parenthetical statement preceding the standard provision. When a standard provision is determined to be applicable in accordance with the applicability statement, the use of such standard provision is mandatory unless a deviation has been approved in accordance with Paragraph 1E of Chapter 1 of Handbook 13. Each grant is required to have a payment provision. Check off the optional standard provisions which are included in the grant. Only those standard provisions which have been checked off are included physically within this grant.

*		<u>Page No.</u>	
1.	OMB Approval Under the Paperwork Reduction Act	10	
2.	Payment - Letter of Credit	11	
3.	Payment - Periodic Advance	13	_____
4.	Payment - Cost Reimbursement	15	_____
5.	Air Travel and Transportation	16	_____
6.	Ocean Shipment of Goods	20	_____
7.	Procurement of Goods and Services	21	_____
8.	AID Eligibility Rules for Goods and Services	27	_____
9.	Subagreements	31	_____
10.	Local Cost Financing	33	_____
11.	Patent Rights	35	_____
12.	Publications	42	_____
13.	Negotiated Indirect Cost Rates - Predetermined	43	_____
14.	Negotiated Indirect Cost Rates - Provisional (Nonprofits)	44	_____
15.	Negotiated Indirect Cost Rates - Provisional (For-profits)	46	_____
16.	Regulations Governing Employees	47	_____
17.	Participant Training	48	_____
18.	Voluntary Population Planning	49	_____
19.	Protection of the Individual as a Research Subject	56	_____
20.	Care of Laboratory Animals	57	_____
21.	Title to and Use of Property (Grantee Title)	58	_____
22.	Title to and Care of Property (U.S. Government Title)	63	_____
23.	Title to and Care of Property (Cooperating Country Title)	67	_____
24.	Cost Sharing (Matching)	71	_____
25.	Use of Pouch Facilities	75	_____
26.	Conversion of United States Dollars to Local Currency	77	_____
27.	Public Notice	78	_____
28.	Rights in Data	79	_____

\*

\* REVISED

34

\* 1. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (AUGUST 1992)

(This provision is applicable whenever any of the nine provisions below containing an information collection requirement is included in the grant.)

Information collection requirements imposed by this grant are covered by OMB approval number 0412-0510; the current expiration date is 7/31/94. Identification of the Standard Provision containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are set forth below.

<u>Standard Provision</u>	<u>Burden Estimate</u>
3 Air Travel and Transportation	1 (hour)
5 - Ocean Shipment of Goods	.5
7 Procurement of Goods and Services	1
11 Patent -	.5
12 Publications	.5
13/14 Negotiated Indirect Cost Rates - Predetermined and Provisional	1
18 Voluntary Population Planning	.5
19 Protection of the Individual as a Research Subject	1
21 Title to and Use of Property (Grantee Title)	1.5

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Procurement Policy and Evaluation Staff (FA/PPE), Agency for International Development, Washington, DC 20523-1435 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

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2. PAYMENT - LETTER OF CREDIT (AUGUST 1992)

\* (This provision is applicable only when the following conditions are met: (i) the total advances under all the grantee's cost-reimbursement contracts and assistance instruments with AID equal or exceed \$50,000 per annum, (ii) AID has, or expects to have, a continuing relationship with the grantee for at least one year; (iii) the grantee has the ability to maintain procedures that will minimize the time elapsing between the transfer of funds and the disbursement thereof; (iv) the grantee's financial management system meets the standards for fund control and accountability required under the standard provision of this grant, entitled "Accounting, Audit, and Records" and, either (v) the foreign currency portion of the total advance under this grant is less than 50% or (vi) the foreign currency portion of the total advance under this grant is more than 50% but more than one foreign currency country is involved.)

(a) Payment under this grant shall be by means of a Letter of Credit (LOC) in accordance with the terms and conditions of the LOC and any instructions issued by AID's Office of Financial Management, Cash Management and Payment Division (FA/FM/CMP).

(b) As long as the LOC is in effect, the terms and conditions of the LOC and any instructions issued by FA/FM/CMP constitute payment conditions of this grant, superseding and taking precedence over any other provision of this grant concerning payment.

(c) Reporting:

(1) A "Financial Status Report" SF-269, shall be prepared on an accrual basis and submitted quarterly no later than 30 days after the end of the period, in an original and two copies to AID/FA/FM/CMP, Washington, D.C. 20523-0209. If the grantee's accounting records are not normally kept on the accrual basis, the grantee shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand. The final report must be submitted within 90 days after the conclusion of the grant to FA/FM/CMP. In cases where grants are Mission funded, the Grantee will forward an information copy to the AID Mission accounting station at the same time the original is mailed to FA/FM/CMP, AID/Washington.

(2) The grantee shall submit an original and one copy of SF-272, "Federal Cash Transactions Report," within 15 working days following the end of each quarter to FA/FM/CMP. Grantees receiving advances totaling more than \$1 million per year shall submit the SF-272 on a monthly basis within 15 working days following the close of the month. Grantees shall report all cash advances in the remarks section of SF-272. Those cash advances in excess of immediate disbursement requirements in the hands of subrecipients or the grantee's field organizations shall be supported by short narrative explanations of actions taken by the grantee to reduce the excess balances. Interest earned shall be reported in Section 13a of the report and shall be paid to AID on a quarterly basis, unless under \$100.00 per annum.

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\* (d) If during the term of the grant, FA/FM/CHP believes that the LOC should be revoked, FA/FM/CHP may, after consultation with the Grant Officer and GC, revoke the LOC by written notification to the grantee. FA/FM/CHP shall provide the grant officer a copy of the revocation notice and recommendation for an alternative method of payment (periodic advance or cost reimbursement) based upon the reasons for the revocation. The grant officer shall immediately amend this agreement to provide for an appropriate alternative method of payment.

(e) Notwithstanding the foregoing, the letter of credit shall be revoked one year after the completion date of the latest grant.

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(END OF STANDARD PROVISION)

\* REVISED

3. PAYMENT - PERIODIC ADVANCE (JANUARY 1988)

(This provision is applicable when the conditions for use of letter of credit cannot be met (including those pertaining to mixed dollar and local currency advances) and when the grantee meets the requirements of paragraph 1.0.6 of Handbook 13.)

- (a) Periodic advances shall be limited to the minimum amounts needed to meet current disbursement needs and shall be scheduled so that the funds are available to the grantee as close as is administratively feasible to the actual disbursements by the grantee for program costs. Cash advances made by the grantee to secondary recipient organizations or the grantee's field organizations shall conform substantially to the same standards of timing and amount as apply to cash advances by AID to the grantee.
- (b) Grantees shall maintain advances in interest bearing accounts. Advances of AID funds to subgrantees shall be maintained in interest bearing accounts.
- (c) Grantees shall submit requests for advances at least monthly on SF-270, "Request for Advance or Reimbursement," in an original and two copies, to the address specified in the Schedule of this grant.
- (d) The grantee shall submit one copy of SF-272, "Federal Cash Transactions Report," 15 working days following the end of each quarter to the payment office address specified in the schedule. Grantees receiving advances totaling more than \$1 million per year shall submit SF-272 on a monthly basis within 15 working days following the close of the month. Grantees shall report in the Remarks section of SF-272 the amount of cash advances in excess of thirty days requirement in the hands of subrecipients or the grantee's overseas field organizations and shall provide short narrative explanations of actions taken by the grantee to reduce the excess balances.
- (e) A "Financial Status Report," SF-269, shall be prepared on an accrual basis by the grantee and submitted quarterly no later than 30 days after the end of the period in an original and two copies to the payment office specified in the schedule. If the grantee's accounting records are not normally kept on the accrual basis, the grantee shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand. The final SF-269 must be submitted to the payment office within 90 days after the conclusion of the grant.

(f) If at any time, the AID Controller determines that the grantee has demonstrated an unwillingness or inability to: (1) establish procedures that will minimize the time elapsing between cash advances and the disbursement thereof, (2) timely report cash disbursements and balances as required by the terms of the grant, and (3) impose the same standards of timing of advances and reporting on any subrecipient or any of the grantee's overseas field organizations; the AID Controller shall advise the grant officer who may suspend or revoke the advance payment procedure.

(END OF STANDARD PROVISION)

4. PAYMENT - COST REIMBURSEMENT (AUGUST 1992)

(This provision is applicable to grants for construction, or to grants where the grantee does not meet the conditions for either a letter of credit or periodic advance payment.)

(a) At the end of each month of this grant, the grantee shall submit an original and two copies of SF-270, "Request for Advance or Reimbursement," to the payment office address specified in the schedule of this grant.

(b) A final SF-270, shall be submitted within 60 days after the conclusion of the grant to the payment office.

\* (c) The reports will be prepared on an accrual basis. However, if the grantee's accounting records are not normally kept on an accrual basis, the grantee shall not be required to convert its accounting system to meet this requirement. \*

(d) Assignment of Claims (otherwise known as assignment of proceeds) is authorized under this grant and will be processed by the payment office.

(END OF STANDARD PROVISION)

\* REVISED

5. AIR TRAVEL AND TRANSPORTATION (AUGUST 1992)

(This provision is applicable when any costs for air travel or transportation are included in the budget.)

- \* (a) The grantee is required to notify the project officer of the proposed itinerary for each planned international trip financed by this grant, by providing the name of the traveller, purpose of the trip, origin/destination (and intervening stops), and dates of travel, as far in advance of the proposed travel as possible, but at least three weeks before travel is planned to commence. International travel, as provided for in the grant, is authorized unless otherwise disapproved by the project officer in writing prior to the commencement of travel. At least one week prior to departure, the grantee shall notify the cognizant U.S. Mission or Embassy, with a copy to the project officer of planned travel, identifying the travellers and dates and times of arrival. \*

(b) Travel to certain countries shall, at AID's option, be funded from U.S.-owned local currency. When AID intends to exercise this option, AID will, after receipt of advice of intent to travel required above, either issue a U.S. Government S.F. 1169, Transportation Request (GTR) which the grantee may exchange for tickets, or AID will issue the tickets directly. Use of such U.S.-owned currencies will constitute a dollar charge to this grant.

(c) All air travel and shipments under this grant are required to be made on U.S. flag air carriers to the extent service by such carriers is available. A U.S. flag air carrier is defined as an air carrier which has a certificate of public convenience and necessity issued by the U.S. Civil Aeronautics Board authorizing operations between the United States and/or its territories and one or more foreign countries.

(d) Use of foreign air carrier service may be deemed necessary if a U.S. flag air carrier otherwise available cannot provide the foreign air transportation needed, or if use of such service will not accomplish the agency's mission. Travel and transportation on non-free world air carriers are not reimbursable under this grant.

(e) U.S. flag air carrier service is considered available even though:

(1) Comparable or a different kind of service can be provided at less cost by a foreign air carrier;

(2) Foreign air carrier service is preferred by or is more convenient for the agency or traveler; or

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(3) Service by a foreign air carrier can be paid for in excess foreign currency, unless U.S. flag air carriers decline to accept excess or near excess foreign currencies for transportation payable only out of such monies.

(f) Except as provided in paragraph b. of this section, U.S. flag air carrier service must be used for all Government-financed commercial foreign air travel if service provided by such carriers is available. In determining availability of a U.S. flag air carrier, the following scheduling principles should be followed unless their application results in the last or first leg of travel to or from the United States being performed by foreign air carrier:

(1) U.S. flag air carrier service available at point of origin should be used to destination or in the absence of direct or through service to the farthest interchange point on a usually traveled route;

(2) Where an origin or interchange point is not served by U.S. flag air carrier, foreign air carrier service should be used only to the nearest interchange point on a usually traveled route to connect with U.S. flag air carrier service; or

(3) Where a U.S. flag air carrier involuntarily reroutes the traveler via a foreign air carrier the foreign air carrier may be used notwithstanding the availability of alternative U.S. flag air carrier service.

(g) For travel between a gateway airport in the United States (the last U.S. airport from which the traveler's flight departs or the first U.S. airport at which the traveler's flight arrives) and a gateway airport abroad (that airport from which the traveler last embarks enroute to the U.S. or at which the traveler first debarks incident to travel from the U.S.), passenger service by U.S. flag air carrier will not be considered available:

(1) Where the gateway airport abroad is the traveler's origin or destination airport, and the use of U.S. flag air carrier service would extend the time in a travel status, including delay at origin and accelerated arrival at destination, by at least 24 hours more than travel by foreign air carrier:

(2) Where the gateway airport abroad is an interchange point, and the use of U.S. flag air carrier service would require the traveler to wait six hours or more to make connections at that point, or delayed departure from or accelerated arrival at the gateway airport in the U.S. would extend the time in a travel status by at least six hours more than travel by foreign air carrier.

(h) For travel between two points outside the U.S. the rules in paragraphs (d) through (f) of this section will be applicable, but passenger service by U.S. flag air carrier will not be considered to be reasonably available:

(1) If travel by foreign air carrier would eliminate two or more aircraft changes enroute;

(2) Where one of the two points abroad is the gateway airport (as defined in paragraph (g) of this section) enroute to or from the United States, if the use of a U.S. flag air carrier would extend the time in a travel status by at least six hours more than travel by foreign air carrier including accelerated arrival at the overseas destination or delayed departure from the overseas origin as well as delay at the gateway airport or other interchange point abroad; or

(3) Where the travel is not part of a trip to or from the United States, if the use of a U.S. flag air carrier would extend the time in a travel status by at least six hours more than travel by foreign air carrier including ~~delay~~ at origin, delay enroute and accelerated arrival at destination.

(f) When travel under either paragraph (g) or (h) of this section involves three hours or less between origin and destination by a foreign air carrier, U.S. flag air carrier service will not be considered available when it involves twice such travel time or more.

(j) Nothing in the above guidelines shall preclude and no penalty shall attend the use of a foreign air carrier which provides transportation under an air transport agreement between the United States and a foreign government, the terms of which are consistent with the international aviation policy goals set forth at 49 U.S.C. 1502(b) and provide reciprocal rights and benefits.

(k) Where U.S. Government funds are used to reimburse the grantee's use of other than U.S. flag air carriers for international transportation, the grantee will include a certification on vouchers involving such transportation which is essentially as follows:

"CERTIFICATION OF UNAVAILABILITY OF U.S. FLAG AIR CARRIERS. I hereby certify that the transportation service for personnel (and their personal effects) or property by certificated air carrier was unavailable for the following reason(s)." (State appropriate reason(s) as set forth above).

(1) International Travel

(1) As used herein, the term "international travel" means travel to all countries other than those within the home country of the traveler.

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(2) The grantee will be reimbursed for travel and the reasonable cost of subsistence, post differentials and other allowances paid to employees in an international travel status in accordance with the grantee's established policies and practices which are uniformly applied to federally financed and other activities of the grantee. The standard for determining the reasonableness of reimbursement for overseas allowance is the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current subsistence, post differentials, and other allowances may be obtained from the grant officer.

(m) This provision will be included in all subgrants and contracts which require air travel and transportation under this grant.

(END OF STANDARD PROVISION)

6. OCEAN SHIPMENT OF GOODS (AUGUST 1992)

\* (This provision is applicable when goods purchased with funds provided under this grant are transported to cooperating countries on ocean vessels whether or not grant funds are used for the transportation.)

(a) At least 50% of the gross tonnage of all goods purchased under this grant and transported to the cooperating countries shall be made on privately owned U.S. flag commercial ocean vessels, to the extent such vessels are available at fair and reasonable rates for such vessels.

(b) At least 50% of the gross freight revenue generated by shipments of goods purchased under this grant and transported to the cooperating countries on dry cargo liners shall be paid to or for the benefit of privately owned U.S. flag commercial ocean vessels to the extent such vessels are available at fair and reasonable rates for such vessels.

(c) When U.S. flag vessels are not available, or their use would result in a significant delay, the grantee may request a determination of non-availability from the AID Transportation Division, Office of Procurement, Washington, D.C. 20523, giving the basis for the request which will relieve the grantee of the requirement to use U.S. flag vessels for the amount of tonnage included in the determination. Shipments made on non-free world ocean vessels are not reimbursable under this grant.

(d) Vouchers submitted for reimbursement which include ocean shipment costs shall contain a certification essentially as follows:

"I hereby certify that a copy of each ocean bill of lading concerned has been submitted to the U.S. Department of Transportation, Maritime Administration, Division of National Cargo, 400 7th Street, S.W., Washington, D.C. 20590, and that such bills of lading state all of the carrier's charges including the basis for calculation such as weight or cubic measurement."

(e) Shipments by voluntary nonprofit relief agencies (i.e., PVOs) shall be governed by this standard provision and by AID Regulation 2, "Overseas Shipments of Supplies by Voluntary Nonprofit Relief Agencies" (22 CFR Part 202).

(f) Shipments financed under this grant must meet applicable eligibility requirements set out in Handbook 1, Supplement B, Chapter 7.

(g) This provision will be included in all subagreements which will finance goods to be shipped on ocean vessels.

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(END OF STANDARD PROVISION)

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45

7. PROCUREMENT OF GOODS AND SERVICES (NOVEMBER 1985)

(This provision is applicable when goods or services are procured under the grant.)

The grantee may use its own procurement policies and practices for the procurement of goods and services under this grant, provided they conform to all of AID's requirements listed below and the standard provision entitled "AID Eligibility Rules for Goods and Services."

(a) General Requirements:

(1) The grantee shall maintain a code or standards of conduct that shall govern the performance of its officers, employees or agents engaged in the awarding and administration of contracts using AID funds. No employee, officer or agent shall participate in the selection, award or administration of a contract in which AID funds are used, where, to that individual's knowledge, the individual or the individual's immediate family, partners, or organization in which the individual or the individual's immediate family or partners has a financial interest or with whom that individual is negotiating or has any arrangement concerning prospective employment. The grantee's officers, employees or agents shall neither solicit nor accept gratuities, favors or anything of monetary value from contractors or potential contractors. Such standards shall provide for disciplinary actions to be applied for violations of such standards by the grantees' officers, employees or agents.

(2) All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The grantee should be alert to organizational conflicts of interest or noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft specifications, requirements, statements of work, invitations for bids and/or requests for proposals should be excluded from competing for such procurements. Awards shall be made to the bidder/offeror whose bid/offer is responsive/responsible to the solicitation and is most advantageous to the grantee, price and other factors considered. Solicitations shall clearly set forth all requirements that the bidder/offeror must fulfill in order to be evaluated by the grantee. Any and all bids/offers may be rejected when it is in the grantee's interest to do so.

(3) All grantees shall establish procurement procedures that provide for, at a minimum, the following procedural requirements:

(i) Proposed procurement actions shall follow a procedure to assure the avoidance of purchasing unnecessary or duplicative items. Where appropriate, an analysis shall be made of lease and purchase alternatives to determine which would be the most economical practical procurement.

(ii) Solicitations for goods and services shall be based upon a clear and accurate description of the technical requirements for the material, product or service to be procured. Such a description shall not, in competitive procurements, contain features which unduly restrict competition. "Brand-name or equal" descriptions may be used as a means to define the performance of other salient requirements of a procurement and when so used the specific features of the named brand which must be met by bidders/offerors shall be clearly specified.

(iii) Positive efforts shall be made by the grantee to utilize small business and minority-owned business sources of supplies and services. Such efforts should allow these sources the maximum feasible opportunity to compete for contracts utilizing AID funds. To permit AID, in accordance with the small business provisions of the Foreign Assistance Act of 1961, as amended, to give United States small business firms an opportunity to participate in supplying commodities and services procured under this grant, the grantee shall to the maximum extent possible provide the following information to the Office of Small Disadvantaged Business Utilization, AID, Washington, D.C. 20523, at least 45 days prior (except where a shorter time is requested of and granted by the Office of Small and Disadvantaged Business Utilization) to placing any order or contract in excess of \$25,000:

- (A) Brief general description and quantity of goods or services;
- (B) Closing date for receiving quotations, proposals, or bids; and
- (C) Address where solicitations or specifications can be obtained.

(iv) The type of procuring instruments used, e.g. fixed price contracts, cost reimbursable contracts, purchase orders, incentive contracts, shall be determined by the grantee but must be appropriate for the particular procurement and for promoting the best interest of the program involved. The "cost-plus-a-percentage-of-cost" method of contracting shall not be used.

(v) Contracts shall be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of a proposed procurement. Consideration shall be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources.

(vi) All proposed sole source contracts or where only one bid or proposal is received in which the aggregate expenditure is expected to exceed \$5,000 shall be subject to prior approval by an appropriate official within the grantee's organization.

(vii) Some form of price or cost analysis should be made in connection with every procurement action. Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices and similar indicia, together with discounts. Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability and allowability.

(viii) Procurement records and files for purchases in excess of \$10,000 shall include the following:

- (A) Basis for contractor selection;
- (B) Justification for lack of competition when competitive bids or offers are not obtained;
- (C) Basis for award cost or price.

(ix) A system for contract administration shall be maintained to ensure contractor conformance with terms, conditions and specifications of the contract, and to ensure adequate and timely followup of all purchases.

(b) Each contract shall contain, in addition to provisions to define a sound and complete contract, the following contract provisions, if applicable, as well as any provision within this grant which requires such inclusion of that provision. Whenever a provision is required to be inserted in a contract under this grant, the grantee shall insert a statement in the contract that in all instances where the U.S. Government or AID is mentioned the grantee's name shall be substituted.

(1) Contracts in excess of \$10,000 shall contain contractual provisions or conditions that will allow for administrative, contractual or legal remedies in instances in which contractors violate or breach contract terms, and provide for such remedial actions as may be appropriate.

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(2) All contracts in excess of \$10,000 shall contain suitable provisions for termination by the grantee including the manner by which termination will be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(3) In all contracts for construction or facility improvement awarded for more than \$100,000, grantees shall observe generally accepted bonding requirements.

(4) All contracts awarded by the grantee or subgrantee to be performed in the United States having a value of more than \$10,000, shall contain a provision requiring compliance with Executive Order 11246, entitled "Equal Employment Opportunity," as amended, and as supplemented in Department of Labor Regulations (41 CFR Part 60).

(5) All contracts and subgrants in excess of \$2,000 for construction or repair to be performed in the United States awarded by the grantee or subgrantee shall include a provision for compliance with the Copeland "Anti-Kick Back" Act (18 U.S.C. 874) as supplemented in Department of Labor Regulations (29 CFR Part 3). This Act provides that each contractor or subgrantee shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which that individual is otherwise entitled. The grantee shall report all suspected or reported violations to AID.

(6) When required by the Federal program legislation, all construction contracts to be performed in the United States awarded by the grantee or subgrantee of more than \$2,000 shall include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 276a to a-7) as supplemented by Department of Labor Regulations (29 CFR Part 5). Under this Act, contractors shall be required to pay wages to laborers and mechanics at a rate not less than the minimum wages specified in a wage determination made by the Secretary of Labor. In addition, contractors shall be required to pay wages not less than once a week. The grantee shall place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation and the award of a contract shall be conditioned upon the acceptance of the wage determination. The grantee shall report all suspected or reported violations to AID.

(7) Where applicable, all contracts awarded by the grantee or subgrantees in excess of \$2,000 for construction contracts to be performed in the United States and its territories and in excess of \$2,500 for other contracts that involve the employment of mechanics or laborers, shall include a provision for compliance with sections 103 and 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330) as supplemented by Department of Labor Regulations (29 CFR Part 5). Under section 103 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work day of 8 hours and a standard workweek of 40 hours. Work in excess of the standard workday or workweek is permissible provided that the worker is compensated at a rate of not less than 1 1/2 times the basic rate of pay for all hours worked in excess of 8 hours in any calendar day or 40 hours in the workweek. Section 107 of the Act is applicable to construction work and provides that no laborer or mechanic shall be required to work in surroundings or under working conditions that are unsanitary, hazardous, or dangerous to the worker's health and safety as determined under construction safety and health standards promulgated by the Secretary of Labor. These requirements do not apply to the purchases of supplies of materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

(8) Contracts, the principal purpose of which is to create, develop or improve products, processes or methods; or for exploration into fields that directly concern public health, safety or welfare; or contracts in the fields of science or technology in which there has been little significant experience outside of work funded by Federal assistance, shall contain a notice to the effect that matters regarding rights to inventions and materials generated under the contract are subject to the regulations included in these grant provisions. The contractor shall be advised as to the source of additional information regarding these matters.

(9) All negotiated contracts over \$10,000 awarded by the grantee shall include a provision to the effect that the grantee, AID, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers and records of the contractor which are directly pertinent to the specific program for the purpose of making audits, examinations, excerpts and transcriptions.

(10) Contracts in excess of \$100,000 to be performed in the United States shall contain a provision that requires the contractor to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act of 1970 (42 U.S.C. 7401) and the Federal Water Pollution Control Act (33 U.S.C. 1251, et seq.) as amended. \* Violations shall be reported to AID and the Regional Office of the Environmental Protection Agency. \*

\* REVISED

504

(11) Contracts which require performance outside the United States shall contain a provision requiring Workmen's Compensation Insurance (42 U.S.C. 1651, et seq.). As a general rule, Department of Labor waivers will be obtained for persons employed outside the United States who are not United States citizens or residents provided adequate protection will be given such persons. The grantee should refer questions on this subject to the AID grant officer.

(END OF STANDARD PROVISION)

8. AID ELIGIBILITY RULES FOR GOODS AND SERVICES (AUGUST 1992)

(This provision is applicable when goods or services are procured under the grant.)

(a) Ineligible and Restricted Goods and Services: If AID determines that the grantee has procured any of the restricted or ineligible goods and services specified below, or has procured goods and services from unauthorized sources, and has received reimbursement for such purpose without the prior written authorization of the grant officer, the grantee agrees to refund to AID the entire amount of the reimbursement. AID's policy on ineligible and restricted goods and services is contained in Chapter 4 of AID Handbook 1, Supplement B, entitled "Procurement Policies".

(1) Ineligible Goods and Services. Under no circumstances shall the grantee procure any of the following under this grant:

- (i) Military equipment,
- (ii) Surveillance equipment,
- (iii) Commodities and services for support of police or other law enforcement activities,
- (iv) Abortion equipment and services,
- (v) Luxury goods and gambling equipment, or
- (vi) Weather modification equipment.

\* (2) Ineligible Suppliers. Funds provided under this grant shall not be used to procure any goods or services furnished by any firms or individuals whose name appears on the "Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs." AID will provide the grantee with a copy of these lists upon request. \*

3. Restricted Goods. The grantee shall not procure any of the following goods and services without the prior written authorization of the grant officer:

- (i) Agricultural commodities,
- (ii) Motor vehicles,
- (iii) Pharmaceuticals,
- (iv) Pesticides,
- (v) Rubber compounding chemicals and plasticizers,
- (vi) Used equipment,
- (vii) U.S. Government-owned excess property, or
- (viii) Fertilizer.

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52+

\* (b) Source and Nationality: The eligibility rules for goods and services based on source and nationality are divided into two categories. One applies when the total procurement element during the life of the grant is over \$250,000, and the other applies when the total procurement element during the life of the grant is not over \$250,000, or the grant is funded under the Development Fund for Africa (DFA) regardless of the amount. The total procurement element includes procurement of all goods (e.g., equipment, materials, supplies) and services. Guidance on the eligibility of specific goods or services may be obtained from the grant officer. AID policies and definitions on source (including origin and componentry) and nationality are contained in Chapter 5 of AID Handbook 1, Supplement B, entitled "Procurement Policies."

(1) For DFA funded grants or when the total procurement element during the life of this grant is valued at \$250,000 or less, the following rules apply:

(1) The authorized source for procurement of all goods and services to be reimbursed under the grant is AID Geographic Code 935, "Special Free World," and such goods and services must meet the source (including origin and componentry) and nationality requirements set forth in Handbook 1, Supp. B, Chapter 5 in accordance with the following order of preference:

- (A) The United States (AID Geographic Code 000),
- (B) The Cooperating Country,
- (C) "Selected Free World" countries (AID Geographic Code 941), and
- (D) "Special Free World" countries (AID Geographic Code 935).

(1) Application of order of preference: When the grantee procures goods and services from other than U.S. sources, under the order of preference in paragraph (b)(1)(1) above, the grantee shall document its files to justify each such instance. The documentation shall set forth the circumstances surrounding the procurement and shall be based on one or more of the following reasons, which will be set forth in the grantee's documentation:

(A) The procurement was of an emergency nature, which would not allow for the delay attendant to soliciting U.S. sources,

(B) The price differential for procurement from U.S. sources exceeded by 50% or more the delivered price from the non-U.S. source.

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53

\* (C) Compelling local political considerations precluded consideration of U.S. sources,

sources, or (D) The goods or services were not available from U.S.

(E) Procurement of locally available goods and services, as opposed to procurement of U.S. goods and services, would best promote the objectives of the Foreign Assistance program under the grant.

(2) When the total procurement element exceeds \$250,000 (unless funded by DFA), the following applies: Except as may be specifically approved or directed in advance by the grant officer, all goods and services financed with U.S. dollars, which will be reimbursed under this grant must meet the source (including origin and componentry) and nationality requirements set forth in Handbook 1, Supp B, Chapter 5 for the authorized geographic code specified in the schedule of this grant. If none is specified, the authorized source is Code 000, the United States. \*

(c) Marine Insurance: The eligibility of marine insurance is determined by the country in which it is placed. Insurance is placed in a country if payment of the insurance premium is made to, and the insurance policy is issued by an insurance company located in that country. Eligible countries for placement are governed by the authorized geographic code, except that if Code 941 is authorized, the Cooperating Country is also eligible. Section 604(d) of the Foreign Assistance Act requires that if a recipient country discriminates by statute, decree, rule, or practice with respect to AID-financed procurement against any marine insurance company authorized to do business in the U. S., then any AID-financed commodity shipped to that country shall be insured against marine risk and the insurance shall be placed in the U. S. with a company or companies authorized to do marine insurance business in the U. S.

(d) Ocean and air transportation shall be in accordance with the applicable provisions contained within this grant.

(e) Printed or Audio-Visual Teaching Materials: If the effective use of printed or audio-visual teaching materials depends upon their being in the local language and if such materials are intended for technical assistance projects or activities financed by AID in whole or in part and if other funds including U.S.-owned or U.S.-controlled local currencies are not readily available to finance the procurement of such materials, local language versions may be procured from the following sources, in order of preference:

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541

- (1) The United States (AID Geographic Code 000).
- (2) The Cooperating Country.
- (3) "Selected Free World" countries (AID Geographic Code 941), and
- (4) "Special Free World" countries (AID Geographic Code 899).

(f) Special Restrictions on the Procurement of Construction or Engineering Services: Section 604(g) of the Foreign Assistance Act provides that AID funds may not be used for "procurement of construction or engineering services from advanced developing countries, eligible under Geographic Code 941, which have attained a competitive capability in international markets for construction services or engineering services." In order to insure eligibility of a Code 941 contractor for construction or engineering services, the grantee shall obtain the grant officer's prior approval for any such contract.

- \* (g) This provision will be included in all subagreements which include procurement of goods or services over \$5,000. \*

(END OF STANDARD PROVISION)

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55

9. SUBAGREEMENTS (AUGUST 1992)

(This provision is applicable when subgrants or cooperative agreements are financed under the grant.)

\* (a) Funds provided under this grant shall not be used to support any subrecipient whose name appears on the "Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs." AID will provide the grantee with a copy of these lists upon request.

(b) All subagreements shall as a minimum contain, in addition to provisions to define a sound and complete agreement, the following provisions as well as any that are specifically required by any other provision in this grant. Whenever a provision within this grant is required to be inserted in a subagreement, the grantee shall insert a statement in the subagreement that in all instances where the U.S. Government is mentioned, the grantee's name will be substituted.

(1) Subagreements in excess of \$10,000 shall contain provisions or conditions that will allow for administrative or legal remedies in instances where subrecipients violate subagreement terms and provide for such remedial action as may be appropriate.

(2) All subagreements in excess of \$10,000 shall contain suitable provisions for termination by the recipient including the manner by which termination will be effected and the basis for settlement. In addition, such subagreements shall describe conditions under which the subagreement may be terminated for default as well as conditions where the subagreement may be terminated because of circumstances beyond the control of the subrecipient.

(3) Subagreements, the principal purpose of which is to create, develop or improve products, processes or methods; or for exploration into fields that directly concern public health, safety or welfare; or subagreements in the field of science or technology in which there has been little significant experience outside of work funded by Federal assistance, shall contain a notice to the effect that matters regarding rights to inventions and materials generated under the subagreement are subject to the regulations contained in the provisions of this grant. The subrecipient shall be advised as to the source of additional information regarding these matters.

(4) A grantee that receives an AID grant and provides \$25,000 or more of it during its fiscal year to a sub-recipient shall follow the guidelines of OMB Circular A-133. The grantee shall ensure that: \*

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\* (i) the nonprofit institution sub-recipients that receive \$25,000 or more have met the audit requirements of OMB Circular A-133, and that sub-recipients subject to OMB Circular A-128 have met the audit requirements of that Circular;

(ii) appropriate corrective action is taken within six months after receipt of the sub-recipient audit report in instances of noncompliance with Federal laws and regulations;

(iii) they consider whether sub-recipients audits necessitate adjustment of the grantee's own records; and

(iv) each sub-recipient is required to permit independent auditors to have access to the records and financial statements as necessary for the grantee to comply with OMB Circular A-133.

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(END OF STANDARD PROVISION)

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57

\* 10. LOCAL COST FINANCING (AUGUST 1992)

This provision is applicable when the total estimated procurement element for the life of the grant is valued over \$250,000 and the grant is not funded under DFA.

(a) Financing local procurement involves the use of appropriated funds to finance the procurement of goods and services supplied by local businesses, dealers or producers, with payment normally being in the currency of the cooperating country.

(b) All locally financed procurements must be covered by source and nationality waivers as set forth in AID Handbook 1, Supplement B, Chapter 5 with the following exceptions:

(1) Locally available commodities of U.S. origin, which are otherwise eligible for financing, if the value of the transaction is estimated not to exceed \$100,000 exclusive of transportation costs.

(2) Commodities of geographic code 935 origin if the value of the transaction does not exceed the local currency equivalent of \$5,000.

(3) Commodities and services available only in the local economy (no specific per transaction value applies to this category). This category includes the following items:

(i) Utilities including fuel for heating and cooking, waste disposal and trash collection;

(ii) Communications - telephone, telex, fax, postal and courier services;

(iii) Rental costs for housing and office space;

(iv) Petroleum, oils and lubricants for operating vehicles and equipment;

(v) Newspapers, periodicals and books published in the cooperating country;

(vi) Other commodities and services and related expenses that, by their nature or as a practical matter, can only be acquired, performed, or incurred in the cooperating country, e.g., vehicle maintenance, hotel accommodations, etc.

(c) All procurements under grants financed with DFA funds and grants with procurement elements of \$250,000 or less are subject to the guidance provided under standard provision "AID Eligibility Rules for Goods and Services."

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(d) Ineligible Goods and Services: Under no circumstances shall the grantee procure any of the following under this grant:

- (1) Military equipment.
- (2) Surveillance equipment.
- (3) Commodities and services for support of police or other law enforcement activities.
- (4) Abortion equipment and services.
- (5) Luxury goods and gambling equipment, or
- (6) Weather modification equipment.

\* (e) Ineligible Suppliers: Funds provided under this grant shall not be used to procure any goods or services furnished by any firm or individual whose name appears on the "Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs." AID will provide the grantee with these lists upon request.

(f) Restricted Goods: The grantee shall not procure any of the following goods and services without the prior written authorization of the grant officer:

- (1) Agricultural commodities.
- (2) Motor vehicles.
- (3) Pharmaceuticals.
- (4) Pesticides.
- (5) Rubber compounding chemicals and plasticizers.
- (6) Used equipment.
- (7) U.S. Government-owned excess property, or
- (8) Fertilizer.

(g) If AID determines that the grantee has procured any of the restricted or ineligible goods and services specified in subparagraphs c. through e. above, or has received reimbursement for such purpose without the prior written authorization of the grant officer, the grantee agrees to refund to AID the entire amount of the reimbursement.

(h) This provision will be included in all subagreements where local procurement of goods or services will be required. \*

(END OF STANDARD PROVISION)

\* REVISED

59

11. PATENT RIGHTS (AUGUST 1992)

(This provision is applicable whenever patentable processes or practices are financed by the grant.)

(a) Definitions.

(1) Invention means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

(2) Subject invention means any invention of the grantee conceived or first actually reduced to practice in the performance of work under this agreement.

(3) Practical application means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(4) Made when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) Small business firm means a domestic small business concern as defined at Section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, shall be used.

(6) Nonprofit organization means a domestic university or other institution of higher education or an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under Section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any domestic nonprofit scientific or any educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights: The grantee may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the grantee retains title, the Federal Government shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

\* (c) Invention Disclosure, Election of Title, and Filing of Patent Applications by Grantee:

(1) The grantee shall disclose each subject invention to AID within two months after the inventor discloses it in writing to grantee personnel responsible for patent matters. The disclosure to AID shall be in the form of a written report and shall identify the grant under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to AID the grantee shall promptly notify AID of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the grantee.

(2) The grantee shall elect in writing whether or not to retain title to any such invention by notifying AID within two years of disclosure to AID. However, in any case where publication, on sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period of election of title may be shortened by AID to a date that is no more than 60 days prior to the end of the statutory period.

(3) The grantee shall file its initial patent application on a subject invention to which it elects to retain title within 1 year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The grantee shall file patent applications in additional countries within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure to AID, election, and filing may, at the discretion of AID, be granted.

(d) Conditions When the Government May Obtain Title:

The grantee shall convey to AID upon written request, title to any subject invention: \*

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- \* (1) If the grantee fails to disclose or elect the subject invention within the times specified in (c) above, or elects not to retain title. AID may only request title within sixty days after learning of the grantee's failure to report or elect within the specified times.
- (2) In those countries in which the grantee fails to file patent applications within the times specified in (c) above; provided, however, that if the grantee has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of AID the grantee shall continue to retain title in that country.
- (3) In any country in which the grantee decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on a patent on a subject invention.

(e) Minimum Rights to Grantee:

- (1) The grantee shall retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title except if the grantee fails to disclose the subject invention within the times specified in (c) above. The grantee's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the grantee is a party and includes the right to grant sublicenses of the same scope to the extent the grantee was legally obligated to do so at the time the grant was awarded. The license is transferable only with the approval of AID except when transferred to the successor of that part of the grantee's business to which the invention pertains.
- (2) The grantee's domestic license may be revoked or modified by AID to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions in 37 CFR Part 4 and agency licensing regulations (if any). This license shall not be revoked in that field of use or the geographical areas in which the grantee has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of AID to the extent the grantee, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

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62-1

\* (3) Before revocation or modification of the license, AID will furnish the grantee written notice of its intention to revoke or modify the license, and the grantee shall be allowed thirty days (or such other time as may be authorized by AID for good cause shown by the grantee) after the notice to show cause why the license should not be revoked or modified. The grantee has the right to appeal, in accordance with applicable regulations in 37 CFR Part 404 and agency regulations, if any, concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of its license.

(f) Grantee Action to Protect the Government's Interest:

(1) The grantee agrees to execute or to have executed and promptly deliver to AID all instruments necessary to (a) establish or conform the rights the Government has throughout the world in those subject inventions to which the grantee elects to retain title, and (b) convey title to AID when requested under paragraph d. above, and to enable the Government to obtain patent protection throughout the world in that subject invention.

(2) The grantee agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the grantee each subject invention made under agreement in order that the grantee can comply with the disclosure provisions of paragraph (c) above, to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1) above. The grantee shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The grantee shall notify AID of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

(4) The grantee agrees to include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: "This invention was made with Government support under (Identify the grant awarded by AID). The Government has certain rights in this invention." \*

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63

\* (g) Subagreements and Contracts: The grantee shall include this standard provision suitably modified to identify the parties, in all subagreements and contracts, regardless of tier, for experimental, developmental, or research work to be performed by a small business firm or nonprofit organization. The subrecipient or contractor shall retain all rights provided for the grantee in this standard provision, and the grantee shall not, as part of the consideration for awarding the contract or subagreement, obtain rights in the contractor's or subrecipient's subject inventions.

(h) Reporting Utilization of Subject Inventions: The grantee agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the grantee or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the grantee, and such other data and information as AID may reasonably specify. The grantee also agrees to provide additional reports as may be requested by AID in connection with any march-in proceedings undertaken by AID in accordance with paragraph (j) of this provision. As required by 35 USC 202(c)(5), AID agrees that, to the extent permitted by law, it shall not disclose such information to persons outside the Government.

(i) Preference for United States Industry: Notwithstanding any other provision of this clause, the grantee agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by AID upon a showing by the grantee or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-In Rights: The grantee agrees that with respect to any subject invention in which it has acquired title, AID has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental agency regulations, to require the grantee, an assignee or exclusive licensee of a subject invention to grant a non-exclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the grantee, assignee, or exclusive licensee refuses such a request, AID has the right to grant such a license itself if AID determines that: \*

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64

\* (1) Such action is necessary because the grantee or assignee has not taken or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the grantee, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the grantee, assignee, or licensees; or

(4) Such action is necessary because the agreement required by paragraph (1) of this clause has not been obtained or waived or because a license of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for Grants with Nonprofit Organizations:  
If the grantee is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of AID, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided that such assignee shall be subject to the same provisions as the grantee.

(2) The grantee shall share royalties collected on a subject invention with the inventor including Federal employee coinventors, when AID deems it appropriate when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the grantee with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, shall be utilized for the support of scientific research or education.

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms, and it will give preference to a small business firm when licensing a subject invention if the grantee determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the grantee is also satisfied that the small business firm has the capability and resources

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\* to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the grantee. However, the grantee agrees that the Secretary of Commerce may review the grantee's licensing program and decisions regarding small business applicants, and the grantee shall negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the grantee could take reasonable steps to more effectively implement the requirements of this subparagraph (k)(4). \*

(1) Communications: Communications concerning this provision shall be addressed to the grant officer at the address shown in this grant.

(END OF STANDARD PROVISION)

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12. PUBLICATIONS (AUGUST 1992)

(This provision is applicable when publications are financed under the grant.)

- \* (a) AID shall be prominently acknowledged in all publications, videos or other information/media products funded or partially funded through this grant, and the product shall state that the views expressed by the author(s) do not necessarily reflect those of AID. Acknowledgements should identify the sponsoring AID Office and Bureau or Mission as well as the U.S. Agency for International Development substantially as follows:

"This [publication, video or other information/media product (specify)] was made possible through support provided by the Office of \_\_\_\_\_, Bureau for \_\_\_\_\_, U.S. Agency for International Development, under the terms of Grant No. \_\_\_\_\_. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development."

(b) Unless the grantee is instructed otherwise by the cognizant technical office, publications, videos or other information/media products funded under this grant and intended for general readership or other general use will be marked with the AID logo and/or U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT appearing either at the top or at the bottom of the front cover or, if more suitable, on the first inside title page for printed products, and in equivalent appropriate location in videos or other information/media products. Logos and markings of co-sponsors or authorizing institutions should be similarly located and of similar size and appearance.

(c) The grantee shall provide the AID project officer and POL/CDIE, Room 215, SA-18, Washington, DC 20523-1802, with one copy each of all published works developed under the grant and with lists of other written work produced under the grant. \*

(d) In the event grant funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost shall be credited to the grant unless the schedule of the grant has identified the profits or royalties as program income.

(e) Except as otherwise provided in the terms and conditions of the grant, the author or the recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of or under this grant, but AID reserves a royalty-free nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use the work for Government purposes.

(END OF STANDARD PROVISION)

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67

13. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (AUGUST 1992)

\* (This provision is applicable to educational or nonprofit institutions whose indirect cost rate(s) under this grant are on a predetermined basis.)

(a) The allowable indirect costs under this grant shall be obtained by applying predetermined indirect cost rate(s) to the base(s) agreed upon by the parties, as specified in the schedule of this grant.

(b) Not later than 13 months after the close of the grantee's fiscal year, the grantee shall submit to the cognizant Government Audit Activity the required OMB Circular A-133 audit, a proposed predetermined indirect cost rate(s), and supporting cost data. In the event AID is the cognizant agency or no cognizant agency has been designated, the grantee shall submit a copy of the proposed predetermined indirect cost rate(s) and supporting cost data to the AID Inspector General, Washington, DC 20523, and to the Overhead and Special Costs - Contract Closeout Branch, Office of Procurement, Washington, DC 20523. The proposed rate(s) shall be based on the grantee's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rate(s) shall begin as soon as practical after receipt of the grantee's proposal. \*

(c) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the provisions of the applicable cost principles in effect on the date of this grant.

(d) Rates for subsequent periods shall be negotiated and the results of each negotiation shall be set forth in a written indirect cost rate agreement executed by both parties. Such agreement shall be automatically incorporated into this grant upon execution and shall specify (1) the agreed upon predetermined rate(s), (2) the base(s) to which the rate(s) apply, (3) the fiscal year (unless the parties agree to a different period) for which the rate(s) apply, and (4) the specific items treated as direct costs or any changes in the items previously agreed to be direct costs. The indirect cost rate agreement shall not change any monetary ceiling, grant obligation, or specific cost allowance or disallowance provided for in this grant.

(e) Pending establishment of predetermined indirect costs rate(s) for any fiscal year or different period agreed to by the parties, the grantee shall be reimbursed either at the rate(s) fixed for the previous fiscal year or other period or at billing rate(s) acceptable to the AID grant officer subject to appropriate adjustment when the final rate(s) for the fiscal year or other period are established.

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687

14. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (AUGUST 1992)

\* (This provision is applicable to any EDUCATIONAL OR NONPROFIT INSTITUTION which does not have predetermined indirect cost rate(s); however, it shall also be included when the NEGOTIATED INDIRECT COST RATES - PREDETERMINED standard provision is used.)

(a) A provisional indirect cost rate(s) shall be established for each of the grantee's accounting periods during the term of this grant. Pending establishment of a final rate(s), the parties have agreed that provisional payments on account of allowable indirect costs shall be at the rate(s), on the base(s), and for the periods shown in the schedule of this grant.

(b) Not later than 13 months after the close of the grantee's fiscal year, the grantee shall submit to the cognizant Government Audit Activity, in accordance with the requirements of OMB Circular A-133, an audit report along with proposed final indirect cost rate(s) and supporting cost data. In the event AID is the cognizant agency or no cognizant agency has been designated, the grantee shall submit seven copies of the OMB Circular A-133 audit along with the proposed final indirect cost rate(s) and supporting cost data to the AID Inspector General, Washington, DC 20523, and a copy to the Overhead and Special Costs - Contract Closeout Branch, Office of Procurement, Washington, DC 20523. The proposed rate(s) shall be based on the grantee's actual cost experience during that fiscal year. Negotiations of final indirect cost rate(s) shall begin as soon as practical after receipt of the grantee's proposal. \*

(c) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the applicable cost principles in effect on the date of this grant.

(d) The results of each negotiation shall be set forth in a written indirect cost rate agreement executed by both parties. Such agreement shall specify (1) the agreed upon final rate(s), (2) the base(s) to which the rate(s) apply, and (3) the period for which the rate(s) apply. The indirect cost rate agreement shall not change any monetary ceiling, grant obligation, or specific cost allowance or disallowance provided for in this grant.

(e) Pending establishment of final indirect cost rate(s) for any period, the grantee shall be reimbursed either at negotiated provisional rate(s) as provided above or at billing rate(s) acceptable to the grant officer, subject to appropriate adjustment when the final rate(s) for that period are established. To prevent substantial over or under payment, the provisional or billing rate(s) may, at the request of either party, be revised by mutual agreement, either retroactively or prospectively. Any such revision of negotiated provisional rate(s) provided in this standard provision shall be set forth in a modification to this grant.

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69

(f) Any failure by the parties to agree on final rate(s) under this standard provision shall be considered a dispute within the meaning of the standard provision of this grant entitled "Dispute" and shall be disposed of in accordance therewith.

(END OF STANDARD PROVISION)

707

15. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (AUGUST 1992)

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(This provision is applicable to FOR-PROFIT organizations whose indirect cost rate(s) under this grant are on a provisional basis.)

(a) Until final annual indirect cost rate(s) are established for any period, the grantee shall be reimbursed either at the provisional rate(s) for the previous fiscal year or other period, or at billing rates acceptable to the AID grant officer subject to appropriate adjustment when the final rate(s) for the fiscal year or other period are established, depending on the availability of funds.

(b) The allowable indirect costs under this grant shall be obtained by applying final indirect cost rate(s) to the base(s) agreed upon by the parties, as specified in the schedule of this grant.

(c) Final annual indirect cost rate(s) and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (48 CFR Ch.1) in effect for the period covered by the indirect cost rate proposal.

(d) Not later than 90 days after the close of the grantee's fiscal year, the grantee shall submit to the cognizant Government Audit Activity proposed final indirect cost rate(s) and supporting cost data. In the event AID is the cognizant agency or no cognizant agency has been designated, the grantee shall submit a copy of the proposed final indirect cost rate(s) and supporting cost data to the AID Inspector General, Washington, DC 20523, and to the Overhead and Special Costs - Contract Closeout Branch, Office of Procurement, Washington, DC 20523. The proposed rate(s) shall be based on the grantee's actual cost experience during that fiscal year. Negotiations of final indirect cost rate(s) shall begin as soon as practical after receipt of the grantee's proposal.

(e) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the provisions of the applicable cost principles in effect on the date of this grant.

(f) Rates for subsequent periods shall be negotiated and the results of each negotiation shall be set forth in a written indirect cost rate agreement executed by both parties. The agreement shall specify (1) the agreed upon final annual indirect cost rate(s), (2) the basis to which the rate(s) apply, (3) the periods for which the rates apply, and (4) any specific items treated as direct costs or any changes in the items previously agreed to be direct costs. The final indirect cost rate agreement shall not change any monetary ceiling, grant obligation, or specific cost allowance or disallowance provided for in this grant.

(g) Any failure by the parties to agree on any final indirect cost rate(s) under this provision shall be a dispute within the meaning of the Disputes provision.

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(END OF STANDARD PROVISION)

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16. REGULATIONS GOVERNING EMPLOYEES (AUGUST 1992)

(The following applies to the grantee's employees who are not citizens of the cooperating country.)

(a) The grantee's employees shall maintain private status and may not rely on local U.S. Government offices or facilities for support while under this grant.

\* (b) The sale of personal property or automobiles by grantee employees and their dependents in the foreign country to which they are assigned shall be subject to the same limitations and prohibitions which apply to direct-hire AID personnel employed by the Mission, including the rules contained in 22 CFR Part 136, except as this may conflict with host government regulations. \*

(c) Other than work to be performed under this grant for which an employee is assigned by the grantee, no employee of the grantee shall engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned, nor shall the individual make loans or investments to or in any business, profession or occupation in the foreign countries to which the individual is assigned.

(d) The grantee's employees, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.

(e) In the event the conduct of any grantee employee is not in accordance with the preceding paragraphs, the grantee's chief of party shall consult with the AID Mission Director and the employee involved and shall recommend to the grantee a course of action with regard to such employee.

(f) The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen or the discharge from this grant of any third country national when, in the discretion of the Ambassador, the interests of the United States so require.

(g) If it is determined, under either (e) or (f) above, that the services of such employee shall be terminated, the grantee shall use its best efforts to cause the return of such employee to the United States, or point of origin, as appropriate.

(END OF STANDARD PROVISION)

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72+

\* 17. PARTICIPANT TRAINING (AUGUST 1992)

(This provision is applicable when any participant training is financed under the grant.)

(a) Definition: A participant is any non-U.S. individual being trained under this grant outside of that individual's home country.

(b) Application of Handbook 10: Participant training under this grant shall comply with the policies established in AID Handbook 10, Participant Training, except to the extent that specific exceptions to Handbook 10 have been provided in this grant with the concurrence of the Office of International Training. (Handbook 10 may be obtained by submitting a request to the Office of International Training (R&D/OIT), Agency for International Development, Washington, D.C. 20523.)

(c) Orientation: In addition to the mandatory requirements in Handbook 10, grantees are strongly encouraged to provide, in collaboration with the Mission training officer, predeparture orientation (see Chapter 13 of Handbook 10) and orientation in Washington at the Washington International Center (see Chapter 18D of Handbook 10). The latter orientation program also provides the opportunity to arrange for home hospitality in Washington and elsewhere in the United States through liaison with the National Council for International Visitors (NCIV). If the Washington orientation is determined not to be feasible, home hospitality can be arranged in most U.S. cities if a request for such is directed to the grant officer, who will transmit the request to NCIV through R&D/OIT.

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(END OF STANDARD PROVISION)

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73

18. VOLUNTARY POPULATION PLANNING (AUGUST 1986)

(This provision is applicable to all grants involving any aspect of voluntary population planning activities.)

(a) Voluntary Participation:

(1) The grantee agrees to take any steps necessary to ensure that funds made available under this grant will not be used to coerce any individual to practice methods of family planning inconsistent with such individual's moral, philosophical, or religious beliefs. Further, the grantee agrees to conduct its activities in a manner which safeguards the rights, health and welfare of all individuals who take part in the program.

(2) Activities which provide family planning services or information to individuals, financed in whole or in part under this agreement, shall provide a broad range of family planning methods and services available in the country in which the activity is conducted or shall provide information to such individuals regarding where such methods and services may be obtained.

(b) Voluntary Participation Requirements For Sterilization Programs:

(1) None of the funds made available under this grant shall be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any person to practice sterilization.

(2) The grantee shall ensure that any surgical sterilization procedures supported in whole or in part by funds from this grant are performed only after the individual has voluntarily gone to the treatment facility and has given informed consent to the sterilization procedure. Informed consent means the voluntary, knowing assent from the individual after being advised of the surgical procedures to be followed, the attendant discomforts and risks, the benefits to be expected, the availability of alternative methods of family planning, the purpose of the operation and its irreversibility, and the option to withdraw consent anytime prior to the operation. An individual's consent is considered voluntary if it is based upon the exercise of free choice and is not obtained by any special inducement or any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation.

(3) Further, the grantee shall document the patient's informed consent by (i) a written consent document in a language the patient understands and speaks, which explains the basic elements of informed consent, as set out above, and which is signed by the individual and by the attending physician or by the authorized assistant of the attending physician; or (ii) when a patient is unable to read adequately a written certification by the attending physician or by the authorized assistant of the attending physician that the basic elements of informed consent above were orally presented to the patient, and that the patient thereafter consented to the performance of the operation. The receipt of the oral explanation shall be acknowledged by the patient's mark on the certification and by the signature or mark of a witness who shall be of the same sex and speak the same language as the patient.

(4) Copies of informed consent forms and certification documents for each voluntary sterilization procedure must be retained by the grantee for a period of three years after performance of the sterilization procedure.

(c) Prohibition on Abortion-Related Activities:

(1) No funds made available under this grant will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to women to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for abortion.

(2) No funds made available under this grant will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

(d) Ineligibility of Foreign Nongovernmental Organizations That Perform or Actively Promote Abortion As A Method of Family Planning:

(1) The grantee agrees that it will not furnish assistance for family planning under this grant to any foreign nongovernmental organization which performs or actively promotes abortion as a method of family planning in AID-recipient countries or which provides financial support to any other foreign nongovernmental organization that conducts such activities. For purposes of this paragraph d., a foreign nongovernmental organization is a nongovernmental organization which is not organized under the laws of any State of the United States, the District of Columbia or the Commonwealth of Puerto Rico.

(2) Prior to furnishing funds provided under this grant to another nongovernmental organization organized under the laws of any State of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, the grantee shall obtain the written agreement of such organization that the organization shall not furnish assistance for family planning under this grant to any foreign nongovernmental organization except under the conditions and requirements that are applicable to the grantee as set forth in this paragraph (d).

(3) The grantee may not furnish assistance for family planning under this grant to a foreign nongovernmental organization (the subrecipient) unless;

(i) the subrecipient certifies in writing that it does not perform or actively promote abortion as a method of family planning in AID-recipient countries and does not provide financial support to any other foreign nongovernmental organization that conducts such activities, and

(ii) the grantee obtains the written agreement of the subrecipient containing the undertakings described in subparagraph 4., below.

(4) Prior to furnishing assistance for family planning under this grant to a subrecipient, the subrecipient must agree in writing that:

(i) The subrecipient will not, while receiving assistance under this grant, perform or actively promote abortion as a method of family planning in AID-recipient countries or provide financial support to other foreign nongovernmental organizations that conduct such activities.

(ii) The grantee and authorized representatives of AID may, at any reasonable time, (A) inspect the documents and materials maintained or prepared by the subrecipient in the usual course of its operations that describe the family planning activities of the subrecipient, including reports, brochures and service statistics; (B) observe the family planning activity conducted by the subrecipient; (C) consult with family planning personnel of the subrecipient; and (D) obtain a copy of the audited financial statement or report of the subrecipient, if there is one.

(iii) In the event the grantee or AID has reasonable cause to believe that a subrecipient may have violated its undertaking not to perform or actively promote abortion as a method of family planning, the grantee shall review the family planning program of the subrecipient to determine whether a violation of the undertaking has occurred. The subrecipient shall make available to the grantee such books and records and other information as may be reasonably requested in order to conduct the review. AID may also review the family planning program of the subrecipient under these circumstances, and AID shall have access to such books and records and information for inspection upon request.

76x

(iv) The subrecipient shall refund to the grantee the entire amount of assistance for family planning furnished to the subrecipient under this grant in the event it is determined that the certification provided by the subrecipient under subparagraph (3), above, is false.

(v) Assistance for family planning provided to the subrecipient under this grant shall be terminated if the subrecipient violates any undertaking in the agreement required by subparagraphs (3) and (4), and the subrecipient shall refund to the grantee the value of any assistance furnished under this grant that is used to perform or actively promote abortion as a method of family planning.

(vi) The subrecipient may furnish assistance for family planning under this grant to another foreign nongovernmental organization (the sub-subrecipient) only if (A) the sub-subrecipient certifies in writing that it does not perform or actively promote abortion as a method of family planning in AID-recipient countries and does not provide financial support to any other foreign nongovernmental organization that conducts such activities and (B) the subrecipient obtains the written agreement of the sub-subrecipient that contains the same undertakings and obligations to the subrecipient as those provided by the subrecipient to the grantee as described in subparagraphs (4)(i)-(v), above.

(5) Agreements with subrecipients and sub-subrecipients required under subparagraphs (3) and (4) shall contain the definitions set forth in subparagraph (10) of this paragraph (d).

(6) The grantee shall be liable to AID for a refund for a violation of any requirement of this paragraph (d) only if (i) the grantee knowingly furnishes assistance for family planning to a subrecipient who performs or actively promotes abortion as a method of family planning, or (ii) the certification provided by a subrecipient is false and the grantee failed to make reasonable efforts to verify the validity of the certification prior to furnishing assistance to the subrecipient, or (iii) the grantee knows or has reason to know, by virtue of the monitoring which the grantee is required to perform under the terms of this grant, that a subrecipient has violated any of the undertakings required under subparagraph (4) and the grantee fails to terminate assistance for family planning to the subrecipient, or fails to require the subrecipient to terminate such assistance to a sub-subrecipient which violates any undertaking of the agreement required under subparagraph (4)(vi), above. If the grantee finds, in exercising its monitoring responsibility under this grant, that a subrecipient or sub-subrecipient receives frequent requests for the information described in subparagraph (10)(iii)(A)(II), below, the grantee shall verify that this information is being provided properly in accordance with subparagraph (10)(iii)(A)(II) and shall describe to AID the reasons for reaching its conclusion.

(7) In submitting a request to AID for approval of a grantee's decision to furnish assistance for family planning to a subrecipient, the grantee shall include a description of the efforts made by the grantee to verify the validity of the certification provided by the subrecipient. AID may request the grantee to make additional efforts to verify the validity of the certification. AID will inform the grantee in writing when AID is satisfied that reasonable efforts have been made. If AID concludes that these efforts are reasonable within the meaning of subparagraph (6) above, the grantee shall not be liable to AID for a refund in the event the subrecipient's certification is false unless the grantee knew the certification to be false or misrepresented to AID the efforts made by the grantee to verify the validity of the certification.

(8) It is understood that AID also may make independent inquiries, in the community served by a subrecipient or sub-subrecipient, regarding whether it performs or actively promotes abortion as a method of family planning.

(9) A subrecipient must provide the certification required under subparagraph (3) and a sub-subrecipient must provide the certification required under subparagraph (4)(vi) each time a new agreement is executed with the subrecipient or sub-subrecipient furnishing assistance for family planning under the grant.

(10) The following definitions apply for purposes of this paragraph (d):

(i) Abortion is a method of family planning when it is for the purpose of spacing births. This includes, but is not limited to, abortions performed for the physical or mental health of the mother but does not include abortions performed if the life of the mother would be endangered if the fetus were carried to term or abortions performed following rape or incest (since abortion under these circumstances is not a family planning act).

(ii) To perform abortions means to operate a facility where abortions are performed as a method of family planning. Excluded from this definition are clinics or hospitals which do not include abortion in their family planning programs.

(iii) To actively promote abortion means for an organization to commit resources, financial or other, in a substantial or continuing effort to increase the availability or use of abortion as a method of family planning.

(A) This includes, but is not limited to, the following:

(I) Operating a family planning counseling service that includes, as part of the regular program, providing advice and information regarding the benefits and availability of abortion as a method of family planning;

(II) Providing advice that abortion is an available option in the event other methods of family planning are not used or are not successful or encouraging women to consider abortion (passively responding to a question regarding where a safe, legal abortion may be obtained is not considered active promotion if the question is specifically asked by a woman who is already pregnant, the woman clearly states that she has already decided to have a legal abortion, and the family planning counselor reasonably believes that the ethics of the medical profession in the country require a response regarding where it may be obtained safely);

(III) Lobbying a foreign government to legalize or make available abortion as a method of family planning or lobbying such a government to continue the legality of abortion as a method of family planning;

(IV) Conducting a public information campaign in AID-recipient countries regarding the benefits and/or availability of abortion as a method of family planning.

(B) Excluded from the definition of active promotion of abortion as a method of family planning are referrals for abortion as a result of rape, incest or if the life of the mother would be endangered if the fetus were carried to term.

(C) Action by an individual acting in the individual's capacity shall not be attributed to an organization with which the individual is associated, provided that the organization neither endorses nor provides financial support for the action and takes reasonable steps to ensure that the individual does not improperly represent that the individual is acting on behalf of the organization.

(iv) To furnish assistance to a foreign nongovernmental organization means to provide financial support under this grant to the family planning program of the organization, and includes the transfer of funds made available under this grant or goods or services financed with such funds, but does not include the purchase of goods or services from an organization or the participation of an individual in the general training programs of the grantee, subrecipient or sub-subrecipient.

(v) To control an organization means the possession of the power to direct or cause the direction of the management and policies of an organization.

(11) In determining whether a foreign nongovernmental organization is eligible to be a subrecipient or sub-subrecipient of assistance for family planning under this grant, the action of separate nongovernmental organizations shall not be imputed to the subrecipient or sub-subrecipient, unless, in the judgment of AID, a separate nongovernmental organization is being used as a sham to avoid the restrictions of this paragraph (d). Separate nongovernmental organizations are those that have distinct legal existence in accordance with the laws of the countries in which they are organized. Foreign organizations that are separately organized shall not be considered separate, however, if one is controlled by the other. The grantee may request AID's approval to treat as separate the family planning activities of two or more organizations, which would not be considered separate under the preceding sentence, if the grantee believes, and provides a written justification to AID therefor, that the family planning activities of the organizations are sufficiently distinct as to warrant not imputing the activity of one to the other.

(12) Assistance for family planning may be furnished under this grant by a grantee, subrecipient or sub-subrecipient to a foreign government even though the government includes abortion in its family planning program, provided that no assistance may be furnished in support of the abortion activity of the government and any funds transferred to the government shall be placed in a segregated account to ensure that such funds may not be used to support the abortion activity of the government.

(13) The requirements of this paragraph are not applicable to family planning assistance furnished to a foreign nongovernmental organization which is engaged primarily in providing health services if the objective of the assistance is to finance integrated health care services to mothers and children and birth spacing or family planning is one of several health care services being provided by the organization as part of an integrated system of health service delivery.

(e) The grantee shall insert paragraphs (a), (b), (c), and (e) of this provision in all subsequent subagreements and contracts involving family planning or population activities which will be supported in whole or part from funds under this grant. Paragraph (d) shall be inserted in subagreements and sub-subagreements in accordance with the terms of paragraph (d). The term subagreement means subgrants and subcooperative agreements.

(END OF STANDARD PROVISION)

807

19. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (AUGUST 1992)

(This provision is applicable when human subjects are involved in research financed by the grant.)

- \* (a) Safeguarding the rights and welfare of human subjects involved in research supported by AID is the responsibility of the grantee. It is the policy of AID that no work shall be initiated under any grant for the support of research involving human subjects unless the research is given initial and continuing review and approval by an appropriate committee of the grantee. This review shall assure that (1) the rights and welfare of the individuals involved are adequately protected, (2) the methods used to obtain informed consent are adequate and appropriate, and (3) the risks and potential medical benefits of the investigation are assessed.
- (b) The grantee must provide written assurance to AID that it will abide by this policy for all research involving human subjects supported by AID. This assurance shall consist of a written statement of compliance with the requirements regarding initial and continuing review of research involving human subjects and a description of the organization's review committee structure, its review procedures, and the facilities and personnel available to protect the health and safety of human subjects. In addition to providing the assurance, the grantee must also certify to AID for each proposal involving human subjects that its committee has reviewed and approved the proposed research before any work may be initiated.
- (c) Since the welfare of the subject individual is a matter of concern to AID as well as to the grantee; AID advisory groups, consultants, and staff may independently review all research involving human subjects, and prohibit research which presents unacceptable hazards. This provision, however, shall not derogate in any manner from the responsibility of the grantee set forth herein.
- (d) All of the above provisions apply to any research involving human subjects conducted outside of the United States and, in addition, such overseas research will conform to legal and other requirements governing human research in the country where they are conducted.
- (e) In addition to the procedures set forth above, studies with unmarketed drugs will be carried out in accordance with provisions applicable in the country where the study is conducted. In the United States, the regulations of the Food and Drug Administration will be followed and evidence of such compliance provided to AID.
- (f) Guidance on procedures to safeguard human subjects involved in research is found in 45 CFR Part 46 as well as the AID-specific regulations in 22 CFR Part 225. Compliance with these procedures, except as modified above, is required. \*

(END OF STANDARD PROVISION)

\* REVISED

20. CARE OF LABORATORY ANIMALS (NOVEMBER 1985)

(This provision is applicable when laboratory animals are involved in research performed in the U.S. and financed by the grant.)

(a) Before undertaking performance of any grant involving the use of laboratory animals, the grantee shall register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The grantee shall furnish evidence of such registration to the grant officer.

(b) The grantee shall acquire animals used in research under this grant only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in (a) above.

(c) In the care of any live animals used or intended for use in the performance of this grant, the grantee shall adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animals Resources, National Academy of Sciences - National Research Council, and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard shall be used. The grantee's reports on portions of the grant in which animals were used shall contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The grantee may request registration of the grantee's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the grantee's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff Office, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, Maryland 20782.

(END OF STANDARD PROVISION)

21. TITLE TO AND USE OF PROPERTY (GRANTEE TITLE) (NOVEMBER 1985)

(This provision is applicable when the Government vests title to property in the grantee only.)

Title to all property financed under this grant shall vest in the grantee, subject to the following conditions:

(a) The grantee shall not charge for any depreciation, amortization, or use of any property, title to which remains in the grantee under this provision under this grant or any other U.S. Government agreement, subagreement, contract, or subcontract.

(b) The grantee agrees to use and maintain the property for the purpose of the grant in accordance with the requirements of paragraphs (c), (d), (e), and (f) below.

(c) Real Property:

(1) Real property means land, including land improvements, structures and appurtenances thereto, but excluding movable machinery and equipment.

(2) Use of Real Property:

(1) The grantee shall use the real property for the authorized purpose of the project, as long as it is needed.

(11) The grantee shall obtain approval from AID for the use of real property in other projects when the grantee determines that the property is no longer needed for the purpose of the original program. Use in other programs shall be limited to those under other federally sponsored programs (i.e., grants or other agreements) that have purposes consistent with those authorized for support by AID

(3) Disposition of Real Property: When the real property is no longer needed as provided in (2) above, the grantee shall request disposition instructions from AID or its successor Federal sponsoring agency. AID or the successor Federal sponsoring agency shall observe the following rules in the disposition instructions:

(1) The grantee may be permitted to retain title after it compensates the Federal Government in an amount computed by applying the Federal percentage of participation in the cost of the original program to the fair market value of the property.

(ii) The grantee may be directed to sell the property under guidelines provided by the Federal sponsoring agency and pay the Federal Government an amount computed by applying the Federal percentage of participation in the cost of the original program to the proceeds from sale (after deducting actual and reasonable selling and fix-up expenses, if any, from the sales proceeds). When the grantee is authorized or required to sell the property, proper sales procedures shall be established that provide for competition to the extent practicable and result in the highest possible return.

(iii) The grantee may be directed to transfer title to the property to the Federal Government provided that in such cases the grantee shall be entitled to compensation computed by applying the grantee's percentage of participation in the cost of the program to the current fair market value of the property.

(d) Nonexpendable Property:

(1) Nonexpendable personal property means tangible personal property having a useful life of more than two years and an acquisition cost of \$500 or more per unit.

(2) Use of Nonexpendable Personal Property:

(1) The grantee shall use the property in the program for which it was acquired as long as needed, whether or not the program continues to be supported by Federal funds. When no longer needed for the original program, the grantee shall use the property in connection with its other federally sponsored activities in the following order of priority:

(A) Activities sponsored by AID

(B) Activities sponsored by other Federal agencies.

(ii) Shared use - During the time that nonexempt nonexpendable personal property is held for use on the program for which it was acquired the grantee shall make it available for use on other programs if such other use will not interfere with the work on the program for which the property was originally acquired. First preference for such other use shall be given to other programs sponsored by AID; second preference shall be given to programs sponsored by other Federal agencies. User charges should be considered if appropriate.

(3) Disposition Of Nonexpendable Personal Property - With A Unit Acquisition Cost Of Less Than \$1,000: The grantee may use the property for other activities without reimbursement to the Federal Government or sell the property and retain the proceeds.

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847

(4) Disposition Of Nonexpendable Personal Property With A Unit Acquisition Cost Of \$1,000 Or More:

(i) The grantee agrees to report such items to the grant officer from time to time as they are acquired and to maintain a control system which will permit their ready identification and location.

(ii) The grantee may retain the property for other uses provided that compensation is made to AID or its successor. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the original program to the current fair market value of the property. If the grantee has no need for the property and the property has further use value, the grantee shall request disposition instructions from AID

(iii) AID shall determine whether the property can be used to meet AID requirements. If no requirement exists within AID the availability of the property shall be reported to the General Services Administration by AID to determine whether a requirement for the property exists in other Federal agencies. AID shall issue instructions to the grantee no later than 120 days after the grantee's request and the following procedures shall govern:

(A) If so instructed or if disposition instructions are not issued within 120 calendar days after the grantee's request, the grantee shall sell the property and reimburse AID an amount computed by applying to the sales proceeds that percentage of Federal participation in the cost of the original program. However, the grantee shall be permitted to deduct and retain from the Federal share \$100 or ten percent of the proceeds, whichever is greater, for the grantee's selling and handling expenses.

(B) If the grantee is instructed to ship the property elsewhere, the grantee shall be reimbursed by the benefiting Federal agency with an amount which is computed by applying the percentage of the grantee's participation in the cost of the original grant program to the current fair market value of the property, plus any reasonable shipping or interim storage costs incurred.

(C) If the grantee is instructed to otherwise dispose of the property, the grantee shall be reimbursed by AID for such costs incurred in its disposition.

(e) Expendable Personal Property:

(1) Expendable personal property means all tangible personal property other than nonexpendable property.

(2) The grantee shall use the expendable personal property for the authorized purpose of the grant program, as long as it is needed.

(3) If there is a residual inventory of such property exceeding \$1,000 in total aggregate fair market value, upon termination or completion of the grant and the property is not needed for any other federally sponsored program, the grantee shall retain the property for use on nonfederally sponsored activities, or sell it, but must in either case, compensate the Federal Government for its share. The amount of compensation shall be computed in the same manner as nonexpendable personal property.

(f) The grantee's property management standards for nonexpendable personal property shall include the following procedural requirements:

(1) Property records shall be maintained accurately and shall include:

(i) A description of the property.

(ii) Manufacturer's serial number, model number, Federal stock number, national stock number, or other identification number.

(iii) Source of the property, including grant or other agreement number.

(iv) Whether title vests in the grantee or the Federal Government.

(v) Acquisition date and cost.

(vi) Percentage (at the end of the budget year) of Federal participation in the cost of the project or program for which the property was acquired.

(vii) Location, use, and condition of the property and the date the information was reported.

(viii) Unit acquisition cost.

(ix) Ultimate disposition data, including date of disposal and sales price or the method used to determine current fair market value where the grantee compensates AID for its share.

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86+

(2) A physical inventory of property shall be taken and the results reconciled with the property records at least once every two years. Any differences between quantities determined by the physical inspection and those shown in the accounting records shall be investigated to determine the causes of the difference. The grantee shall in connection with the inventory, verify the existence, current utilization, and continued need for the property. The inventory listing shall be retained as documentation in accordance with the standard provision of this grant entitled "Accounting, Audit, and Records."

(3) A control system shall be in effect to insure adequate safeguards to prevent loss, damage, or theft of the property. Any loss, damage, or theft of nonexpendable property shall be investigated and fully documented.

(4) Adequate maintenance procedures shall be implemented to keep the property in good condition.

(5) Where the grantee is authorized or required to sell the property, proper sales procedures shall be established which would provide for competition to the extent practicable and result in the highest possible return.

(END OF STANDARD PROVISION)

22. TITLE TO AND CARE OF PROPERTY (U.S. GOVERNMENT TITLE) (NOVEMBER 1985)

(This provision is applicable when title to property is vested in the U.S. Government.)

(a) Property, title to which vests in the Government under this grant, whether furnished by the Government or acquired by the grantee, is subject to this provision and is hereinafter collectively referred to as "Government property." Title to Government property shall not be affected by the incorporation or attachment thereof to any property not owned by the Government, nor shall such Government property, or any part thereof, be or become a fixture or lose its identity as personal property by reason of affixation to any real property.

(b) Use of Government Property: Government property shall, unless otherwise provided herein or approved by the grant officer, be used only for the performance of this grant.

(c) Control, Maintenance and Repair of Government Property:

(1) The grantee shall maintain and administer in accordance with sound business practice a program for the maintenance, repair, protection, and preservation of Government property so as to assure its full availability and usefulness for the performance of this grant. The grantee shall take all reasonable steps to comply with all appropriate directions or instructions which the grant officer may prescribe as reasonably necessary for the protection of the Government property.

(2) The grantee shall submit, for review and written approval of the grant officer, a records system for property control and a program for orderly maintenance of Government property; however, if the grantee's property control and maintenance system has been reviewed and approved by another Federal department or agency pursuant to Attachment N of OMB Circular No. A-110, the grantee shall furnish the grant officer proof of such approval in lieu of another approval submission.

(3) Property Control: The property control system shall include but not be limited to the following:

(1) Identification of each item of Government property acquired or furnished under the grant by a serially controlled identification number and by description of item. Each item must be clearly marked "Property of U.S. Government."

(11) The price of each item of property acquired or furnished under this grant.

(iii) The location of each item of property acquired or furnished under this grant.

(iv) A record of any usable components which are permanently removed from items of Government property as a result of modification or otherwise.

(v) A record of disposition of each item acquired or furnished under the grant.

(vii) Date of order and receipt of any item acquired or furnished under the grant.

(viii) The official property control records shall be kept in such condition that at any stage of completion of the work under this grant, the status of property acquired or furnished under this grant may be readily ascertained. A report of current status of all items of property acquired or furnished under the grant shall be submitted yearly concurrently with the annual report.

(4) Maintenance Program: The grantee's maintenance program shall be consistent with sound business practice, the terms of the grant, and provide for:

(i) disclosure of need for and the performance of preventive maintenance,

(ii) disclosure and reporting of need for capital type rehabilitation, and

(iii) recording of work accomplished under the program:

(A) Preventive maintenance - Preventive maintenance is maintenance generally performed on a regularly scheduled basis to prevent the occurrence of defects and to detect and correct minor defects before they result in serious consequences.

(B) Records of maintenance - The grantee's maintenance program shall provide for records sufficient to disclose the maintenance actions performed and deficiencies discovered as a result of inspections.

(C) A report of status of maintenance of Government property shall be submitted annually concurrently with the annual report.

(d) Risk of Loss:

(1) The grantee shall not be liable for any loss of or damage to the Government property, or for expenses incidental to such loss or damage except that the grantee shall be responsible for any such loss or damage (including expenses incidental thereto):

(i) Which results from willful misconduct or lack of good faith on the part of any of the grantee's directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives, who have supervision or direction of all or substantially all of the grantee's business, or all or substantially all of the grantee's operation at any one plant, laboratory, or separate location in which this grant is being performed;

(ii) Which results from a failure on the part of the grantee, due to the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in (i) above:

(A) to maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection, and preservation of Government property as required by (a) above, or

(B) to take all reasonable steps to comply with any appropriate written directions of the grant officer under (c) above;

(iii) For which the grantee is otherwise responsible under the express terms designated in the schedule of this grant;

(iv) Which results from a risk expressly required to be insured under some other provision of this grant, but only to the extent of the insurance so required to be procured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or

(v) Which results from a risk which is in fact covered by insurance or for which the grantee is otherwise reimbursed, but only to the extent of such insurance or reimbursement;

(vi) Provided, that, if more than one of the above exceptions shall be applicable in any case, the grantee's liability under any one exception shall not be limited by any other exception.

(2) The grantee shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provision for a reserve, covering the risk of loss of or damage to the Government property, except to the extent that the Government may have required the grantee to carry such insurance under any other provision of this grant.

(3) Upon the happening of loss or destruction of or damage to the Government property, the grantee shall notify the grant officer thereof, shall take all reasonable steps to protect the Government property from further damage, separate the damaged and undamaged Government property, put all the Government property in the best possible order, and furnish to the grant officer a statement of:

- (i) The lost, destroyed, or damaged Government property;
- (ii) The time and origin of the loss, destruction, or damage;
- (iii) All known interests in commingled property of which the Government property is a part; and
- (iv) The insurance, if any, covering any part of or interest in such commingled property.

(4) The grantee shall make repairs and renovations of the damaged Government property or take such other action as the grant officer directs.

(5) In the event the grantee is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the Government property, it shall use the proceeds to repair, renovate or replace the Government property involved, or shall credit such proceeds against the cost of the work covered by the grant, or shall otherwise reimburse the Government, as directed by the grant officer. The grantee shall do nothing to prejudice the Government's right to recover against third parties for any such loss, destruction, or damage, and upon the request of the grant officer, shall, at the Government's expense, furnish to the Government all reasonable assistance and cooperation (including assistance in the prosecution of suits and the execution of instruments or assignments in favor of the Government) in obtaining recovery.

(e) Access: The Government, and any persons designated by it, shall at all reasonable times have access to the premises wherein any Government property is located, for the purpose of inspecting the Government property.

(f) Final Accounting and Disposition of Government Property: Upon completion of this grant, or at such earlier dates as may be fixed by the grant officer, the grantee shall submit, in a form acceptable to the grant officer, inventory schedules covering all items of Government property not consumed in the performance of this grant or not theretofore delivered to the Government, and shall prepare, deliver, or make such other disposition of the Government property as may be directed or authorized by the grant officer.

(g) Communications: All communications issued pursuant to this provision shall be in writing.

(END OF STANDARD PROVISION)

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23. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (NOVEMBER 1985)

(This provision is applicable to property titled in the name of the cooperating country or such public or private agency as the cooperating country government may designate.)

(a) Except as modified by the schedule of this grant, title to all equipment, materials and supplies, the cost of which is reimbursable to the grantee by AID or by the cooperating country, shall at all times be in the name of the cooperating country or such public or private agency as the cooperating country may designate, unless title to specified types or classes of equipment is reserved to AID under provisions set forth in the schedule of this grant. All such property shall be under the custody and control of grantee until the owner of title directs otherwise or completion of work under this grant or its termination, at which time custody and control shall be turned over to the owner of title or disposed of in accordance with its instructions. All performance guarantees and warranties obtained from suppliers shall be taken in the name of the title owner.

(b) The grantee shall maintain and administer in accordance with sound business practice a program for the maintenance, repair, protection, and preservation of Government property so as to assure its full availability and usefulness for the performance of this grant. The grantee shall take all reasonable steps to comply with all appropriate directions or instructions which the grant officer may prescribe as reasonably necessary for the protection of the Government property.

(c) The grantee shall prepare and establish a program, to be approved by the appropriate AID Mission, for the receipt, use, maintenance, protection, custody and care of equipment, materials and supplies for which it has custodial responsibility, including the establishment of reasonable controls to enforce such program. The grantee shall be guided by the following requirements:

(i) Property Control: The property control system shall include but not be limited to the following:

(1) Identification of each item of cooperating country property acquired or furnished under the grant by a serially controlled identification number and by description of item. Each item must be clearly marked "Property of (insert name of cooperating country)."

(ii) The price of each item of property acquired or furnished under this grant.

(iii) The location of each item of property acquired or furnished under this grant.

(iv) A record of any usable components which are permanently removed from items of cooperating country property as a result of modification or otherwise.

(v) A record of disposition of each item acquired or furnished under the grant.

(vi) Date of order and receipt of any item acquired or furnished under the grant.

(vii) The official property control records shall be kept in such condition that at any stage of completion of the work under this grant, the status of property acquired or furnished under this grant may be readily ascertained. A report of current status of all items of property acquired or furnished under the grant shall be submitted yearly concurrently with the annual report.

(2) Maintenance Program: The grantee's maintenance program shall be consistent with sound business practice, the terms of the grant, and provide for:

(i) disclosure of need for and the performance of preventive maintenance,

(ii) disclosure and reporting of need for capital type rehabilitation, and

(iii) recording of work accomplished under the program:

(A) Preventive maintenance - Preventive maintenance is maintenance generally performed on a regularly scheduled basis to prevent the occurrence of defects and to detect and correct minor defects before they result in serious consequences.

(B) Records of maintenance - The grantee's maintenance program shall provide for records sufficient to disclose the maintenance actions performed and deficiencies discovered as a result of inspections.

(C) A report of status of maintenance of cooperating country property shall be submitted annually concurrently with the annual report.

(d) Risk of Loss:

(1) The grantee shall not be liable for any loss of or damage to the cooperating country property, or for expenses incidental to such loss or damage except that the grantee shall be responsible for any such loss or damage (including expenses incidental thereto):

(i) Which results from willful misconduct or lack of good faith on the part of any of the grantee's directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives, who have supervision or direction of all or substantially all of the grantee's business, or all or substantially all of the grantee's operation at any one plant, laboratory, or separate location in which this grant is being performed;

(ii) Which results from a failure on the part of the grantee, due to the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in (i) above:

(A) to maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection, and preservation of cooperating country property as required by (i) above, or

(B) to take all reasonable steps to comply with any appropriate written directions of the grant officer under (b) above;

(iii) For which the grantee is otherwise responsible under the express terms designated in the schedule of this grant;

(iv) Which results from a risk expressly required to be insured under some other provision of this grant, but only to the extent of the insurance so required to be procured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or

(v) Which results from a risk which is in fact covered by insurance or for which the grantee is otherwise reimbursed, but only to the extent of such insurance or reimbursement;

(vi) Provided, that, if more than one of the above exceptions shall be applicable in any case, the grantee's liability under any one exception shall not be limited by any other exception.

(2) The grantee shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provision for a reserve, covering the risk of loss of or damage to the cooperating country property, except to the extent that AID may have required the grantee to carry such insurance under any other provision of this grant.

(3) Upon the happening of loss or destruction of or damage to the cooperating country property, the grantee shall notify the grant officer thereof, shall take all reasonable steps to protect the cooperating country property from further damage, separate the damaged and undamaged cooperating country property, put all the cooperating country property in the best possible order, and furnish to the grant officer a statement of:

(i) The lost, destroyed, or damaged cooperating country property;

(ii) The time and origin of the loss, destruction, or damage;

(iii) All known interests in commingled property of which the cooperating country property is a part; and

(iv) The insurance, if any, covering any part of or interest in such commingled property.

(4) The grantee shall make repairs and renovations of the damaged cooperating country property or take such other action as the grant officer directs.

(5) In the event the grantee is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the cooperating country property, it shall use the proceeds to repair, renovate or replace the cooperating country property involved, or shall credit such proceeds against the cost of the work covered by the grant, or shall otherwise reimburse AID, as directed by the grant officer. The grantee shall do nothing to prejudice AID's right to recover against third parties for any such loss, destruction, or damage, and upon the request of the grant officer, shall, at the Government's expense, furnish to AID all reasonable assistance and cooperation (including assistance in the prosecution of suits and the execution of instruments or assignments in favor of the Government) in obtaining recovery.

(e) Access: AID, and any persons designated by it, shall at all reasonable times have access to the premises wherein any cooperating country property is located, for the purpose of inspecting the cooperating country property.

(f) Final Accounting and Disposition of Cooperating Country Property: Within 90 days after completion of this grant, or at such other date as may be fixed by the grant officer, the grantee shall submit to the grant officer an inventory schedule covering all items of equipment, materials and supplies under the grantee's custody, title to which is in the cooperating country or public or private agency designated by the cooperating country, which have not been consumed in the performance of this grant. The grantee shall also indicate what disposition has been made of such property.

(g) Communications: All communications issued pursuant to this provision shall be in writing.

(END OF STANDARD PROVISION)

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95

24. COST SHARING (MATCHING) (AUGUST 1992)

(This provision is applicable when the grantee is required to cost share or provide a matching share.)

\* (a) For each year (or funding period) under this grant, the grantee agrees to expend from non-Federal funds an amount at least equal to the amount or percentage of the total expenditures under this grant as specified in the schedule of the grant. The schedule of this grant may also contain restrictions on the application of cost sharing (matching) funds. The schedule takes precedence over the terms of this provision. \*

(b) Eligibility of non-Federal funds applied to satisfy cost sharing (matching) requirements under this grant are set forth below:

(1) Charges incurred by the grantee as project costs. Not all charges require cash outlays by the grantee during the project period; examples are depreciation and use charges for buildings and equipment.

(2) Project costs financed with cash contributed or donated to the grantee by other non-Federal public agencies (may include public international organizations or foreign governments) and institutions, and private organizations and individuals, and

(3) Project costs represented by services and real and personal property, or use thereof, donated by other non-Federal public agencies and institutions, and private organizations and individuals.

(c) All contributions, both cash and in-kind, shall be accepted as part of the grantee's cost sharing (matching) when such contributions meet all of the following criteria:

(1) Are verifiable from the grantee's records;

(2) Are not included as contributions for any other Federally assisted program;

(3) Are necessary and reasonable for proper and efficient accomplishment of project objectives;

(4) Are types of charges that would be allowable under the applicable Federal cost principles;

(5) Are not paid by the Federal Government under another grant or agreement (unless the grant or agreement is authorized by Federal law to be used for cost sharing or matching);

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96+

(6) Are provided for in the approved budget when required by AID;  
and

(7) Conform to other provisions of this paragraph.

(d) Values for grantee in-kind contributions will be established in accordance with the applicable Federal cost principles.

(e) Specific procedures for the grantee in establishing the value of in-kind contributions from non-Federal third parties are set forth below:

(1) Valuation of volunteer services: Volunteer services may be furnished by professional and technical personnel, consultants, and other skilled and unskilled labor. Volunteer services may be counted as cost sharing or matching if the service is an integral and necessary part of an approved program:

(1) Rates for volunteer services: Rates for volunteers should be consistent with those paid for similar work in the grantee's organization. In those instances in which the required skills are not found in the grantee's organization, rates should be consistent with those paid for similar work in the labor market in which the grantee competes for the type of services involved.

(11) Volunteers employed by other organizations: When an employer other than the grantee furnishes the services of an employee, these services shall be valued at the employee's regular rate of pay (exclusive of fringe benefits and overhead costs) provided these services are of the same skill for which the employee is normally paid.

(2) Valuation of donated expendable personal property: Donated expendable personal property includes such items as expendable equipment, office supplies, laboratory supplies or workshop and classroom supplies. Value assessed to expendable personal property included in the cost share (match) should be reasonable and should not exceed the market value of the property at the time of the donation.

(3) Valuation of donated nonexpendable personal property, buildings, and land or use thereof:

(1) The method used for charging cost sharing or matching for donated nonexpendable personal property, buildings and land may differ according to the purpose of the grant as follows:

(A) If the purpose of the grant is to assist the grantee in the acquisition of equipment, buildings or land, the total value of the donated property may be claimed as cost sharing or matching.

(B) If the purpose of the grant is to support activities that require the use of equipment, buildings, or land; depreciation or use charges for equipment and buildings may be made. The full value of equipment or other capital assets and fair rental charges for land may be allowed provided that AID has approved the charges.

(11) The value of donated property will be determined in accordance with the usual accounting policies of the grantee with the following qualifications:

(A) Land and buildings: The value of donated land and buildings may not exceed its fair market value, at the time of donation to the grantee as established by an independent appraiser; and certified by a responsible official of the grantee.

(B) Nonexpendable personal property: The value of donated nonexpendable personal property shall not exceed the fair market value of equipment and property of the same age and condition at the time of donation.

(C) Use of space: The value of donated space shall not exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately owned building in the same locality.

(D) Borrowed equipment: The value of borrowed equipment shall not exceed its fair rental value.

(f) The following requirements pertain to the grantee's supporting records for in-kind contributions from non-Federal third parties:

(1) Volunteer services must be documented and, to the extent feasible, supported by the same methods used by the grantee for its employees.

(2) The basis for determining the valuation for personal services, material, equipment, buildings and land must be documented.

\* (g) Individual expenditures do not have to be shared or matched provided that the total expenditures incurred during the year (or funding period) are shared or matched in accordance with the agreed upon amount or percentage as set forth in the schedule of the grant.

(h) If at the end of any year (or funding period) hereunder, the grantee has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the difference may be applied to reduce the amount of AID funding the following year (or funding period), or, if this grant has expired or been terminated, the difference shall be refunded to AID. \*

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987

(i) Failure to meet the cost sharing (matching) requirements set forth in paragraph (a) above shall be considered sufficient reasons for termination of this grant for cause in accordance with paragraph (a) entitled "For Cause" of the standard provision of this grant entitled "Termination and Suspension".

\* (j) The restrictions on the use of AID funds set forth in the standard provisions of this grant are applicable to expenditures incurred with AID funds provided under this grant. Except for the requirements of this standard provision, the restrictions set forth in the standard provisions of this grant are not applicable to costs incurred by the grantee from non-Federal funds. The grantee will account for the AID funds in accordance with the standard provision of this grant entitled "Accounting, Audit, and Records"; however, in the event of disallowances of expenditures from AID grant funds, the grantee may substitute expenditures made with funds provided from non-Federal sources, provided they are eligible in accordance with all the standard provisions of this grant.

(k) Notwithstanding paragraph (c) of the standard provision of this grant entitled "Refunds", the parties agree that in the event of any disallowance of expenditures from AID grant funds provided hereunder, the grantee may substitute expenditures made with funds provided from non-Federal sources provided they are otherwise eligible in accordance with paragraph (b) of this provision. \*

(END OF STANDARD PROVISION)

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99

25. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision is applicable when activities under the grant will take place outside of the United States.)

(a) Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for AID grantees and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or AID Mission. In consideration of the use of pouch facilities, the grantee and its employees agree to indemnify and hold harmless, the Department of State and AID for loss or damage occurring in pouch transmission:

\* (1) Grantees and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.

(2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see (a)(3) below).

(3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.

(4) Official and personal mail pursuant to a.1. and 2. above sent by pouch should be addressed as follows:

Name of individual or organization (followed by  
letter symbol "G")  
City Name of post (USAID/\_\_\_\_\_)  
Agency for International Development  
Washington, D.C. 20523-0001

(5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may not contain material ineligible for pouch transmission.

(6) AID grantee personnel are not authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

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1004

(b) The grantee shall be responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.

(c) Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or AID Mission.

(END OF STANDARD PROVISION)

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101

26. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY (NOVEMBER 1985)

(This provision is applicable when activities under the grant will take place outside of the United States.)

Upon arrival in the Cooperating Country, and from time to time as appropriate, the grantee's chief of party shall consult with the Mission Director who shall provide, in writing, the procedure the grantee and its employees shall follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

(END OF STANDARD PROVISION)

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102+

\* 27. PUBLIC NOTICES (AUGUST 1992)

It is AID's policy to inform the public as fully as possible of its programs and activities. The grantee is encouraged to give public notice of the receipt of this grant and, from time to time, to announce progress and accomplishments. Press releases or other public notices should include a statement substantially as follows:

"The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide."

The grantee may call on AID's Office of External Affairs for advice regarding public notices. The grantee is requested to provide copies of notices or announcements to the cognizant technical officer and to AID's Office of External Affairs as far in advance of release as possible.

(END OF STANDARD PROVISION)

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103

\* 28. PROVISION ON RIGHTS IN DATA (AUGUST 1992)

(a) Definitions

"Data" means recorded information (including information relating to the research, testing, or development of any drug or device requiring approval for use in the United States), regardless of form or the media on which it may be recorded. In the aggregate these data may be in the form of reports, articles, manuals, or publications. The term includes technical data and computer software. The term does not include financial reports or other information incidental to grant administration.

"Form, fit and function data" means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, as well as data identifying source, size, configuration, mating, and attachment characteristics, functional characteristics, and performance requirements but specifically excludes the source code, algorithm, process, formulae, and flow charts of the software.

"Limited rights" means the rights of the Government in limited rights data as set forth in the following Limited Rights Notice:

— "These data are submitted with limited rights. These data may be reproduced and used by the Government with the limitation that they will not, without written permission of the Grantee, be used for purposes of manufacture nor disclosed outside the Government.

— "This Notice shall be marked on any reproduction of these data, in whole or in part."

"Limited rights data" means data (other than computer software) that embody trade secrets, or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications thereof.

"Restricted computer software" means computer software developed at private expense and that is a trade secret; is commercial or financial and is confidential or privileged; or is published copyrighted computer software, including minor modifications of such computer software.

"Technical data" means data (other than computer software) which are of a scientific or technical nature.

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104

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"Unlimited rights" means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly, in any manner and for any purpose, and to permit others to do so.

(b) Allocation of Rights

(1) Except as provided in paragraph (c) of this provision regarding copyright, the Federal Government shall have unlimited rights in —

- (i) Data first produced in performance of this Grant;
- (ii) Form, fit and function data delivered under this Grant;
- (iii) Data delivered under this Grant (except for restricted computer software) that constitutes manuals or instructional and training material for installation, operation or routine maintenance and repair of items, components, or processes delivered or furnished for use under this Grant; and
- (iv) All other data delivered under this Grant unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (d) of this provision.

(2) The Grantee shall have the right to —

- (i) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Grantee in the performance of this Grant;
- (ii) Protect from unauthorized disclosure and use those data which are limited rights data or restricted computer software to the extent provided in paragraph (d) of this provision;
- (iii) Substantiate use of, add or correct limited rights, restricted rights, or copyright notices;
- (iv) Establish claim to copyright subsisting in data first produced in the performance of this Grant to the extent provided in subparagraph (c) of this provision.

(c) Copyright

(1) Data first produced in the performance of this Grant. The Grantee may establish, without prior approval of AID, claim to copyright subsisting in scientific and technical articles based on or containing data first produced in the performance of this Grant and published in academic, technical or professional journals, symposia proceedings or similar works. The prior express written permission of AID is required to establish claim to copyright subsisting in all other data first produced in performance of this Grant. For computer software and other data the Grantee grants to the Government, and others acting on its behalf, a paid-up nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, prepare derivative works and display publicly by or on behalf of the Government.

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105

\* (2) Data not first produced in the performance of this Grant. The Grantee shall not, without prior written permission of AID incorporate in data delivered under this Grant any data not first produced in the performance under this Grant and which contains the copyright notice of 17 U.S.C. 401 or 402, unless the grantee identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth above in paragraph (c).

(3) Removal of copyright notices. The Government agrees not to remove any copyright notices placed on data delivered under this Grant and to include such notice on all reproductions of such data.

(d) Protection of limited rights data and restricted computer software

When data other than that listed in subparagraph (b)(1)(i), (ii) and (iii) of this provision are specified to be delivered under this Grant and qualify as either limited rights data or restricted computer software, if the Grantee desires to continue protection of such data, the Grantee shall withhold such data and not furnish them to the Government under this Grant. As a condition to this withholding, the Grantee shall identify the data being withheld and furnish form, fit, and function data in lieu thereof.

(e) Subagreements

The Grantee has the responsibility to obtain from subgrantees and those who work in collaboration with the Grantee in performance of this Grant all data and rights necessary to fulfill the Grantee's obligations under this Grant. If a subgrantee or collaborator refuses to accept terms affording the Government such rights, the Grantee shall promptly bring such refusal to the attention of AID and not proceed without authorization from AID.

(f) Relationship to patents

Nothing contained in this provision shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right granted to the Government.

(END OF STANDARD PROVISION)

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106

1. Cooperating Country Worldwide	2. PIO/T No. 936-5600 3692437	3. PIO/T Amend No. Original
4. Project/Activity No. and Title R&D/R Project 936-5600, Innovative Scientific Research II, Grant 10.211, "Assessment of PCR Predictive Test..."	5. Appropriation Symbol(s) 72-1131021.1	
6. Budget Plan Code(s) DDVA-93-16950-CG-11 (341-36-099-04-19-31)		
7. Pro Ag No. or Project Authorization Date Action Memo Approved 4/10/90	8. Obligation Status <input checked="" type="checkbox"/> Administrative Reservation <input type="checkbox"/> Implementing Document	
9. Project Assistance Completion Date (Month, Day, Year) 12/31/99	10. Authorized Agent FA/OP/A/HRN	
11. Type of Action and Governing A.I.D. Handbook [B] A. A.I.D. Contract (HB14) C. PASA/RSSA (HB 12) B. A.I.D. Grant or Cooperative Agreement (HB 13) D. Other	12. Contract/Grant/Cooperative Agreement/Reference Number (if this PIO/T is for an order or a modification to an award) TBD	

13. A.I.D. Funding (Attach a detailed budget in support of column (2) as Attachment A.				
	(1) Previous Total	(2) Increase	(3) Decrease	(4) Total to Date
A. Dollars		45,000		45,000
B. U.S.-Owned Local Currency				0

14. Mission References Mission concurs per two-way memo from USAID/Lima rec'd 2/13/90

15. Instructions to Authorized Agent  
Request that you negotiate a Grant with San Francisco State University in support of its unsolicited research proposal, "Assessment of Pcr Predictive Test for Relapse in American Leishmaniasis(10.211)". The funds in this PIO/T cover the first increment of a total amount of \$150,000; the remaining \$75,000 is expected to be obligated in FY 1994. This PIO/T is in conjunction with another funding request of \$30,000 funded from project 936-5600, BPC-DDVA-16950-KG11. This PIO/T is issued in conjunction with PIO/T # 3692437. Voucher Identification: in each instance of voucher (SF-1034) submission for payment hereunder, the following identification data must appear on the face of the voucher:  
Project No. 936-5600, R&D/R Project No. 10.211  
Project Office: R&D/R  
Budget Plan Code: DDVA-93-16950-CG-11 Obligation Number:

16. Address of Voucher Paying Office Agency for International Development  
FA/FM/CMP/DC, Room 700, SA-2, Washington, D.C. 20523

17. Clearances - Include typed name, office symbol, and date for all clearances  
A. The Project Officer certifies (1) that the specifications in the statement of work or program description are technically adequate, and (2) that (for contract actions only) all program personnel who are defined as procurement officials under 41 U.S.C 423 have signed the Procurement Integrity Certification (OF-333).

Signature R&D/R, Miloslav Rechcigl <i>Miloslav Rechcigl</i>	Date: 4/27/93	Phone No:
B. The statement of work or program description lies within the purview of the initiating office and approved agency programs. Signature: R&D/R, Wayne W. P. Ching <i>Wayne W. P. Ching</i>	Date: 4/23/93	C. Signature: R&D/PO/AE, G. Standroed <i>G. Standroed</i>
D. Funds for the services requested are available Signature: FA/FM/A/NPA, Rose Anderson <i>Rose Anderson</i>	Date:	E. Signature: R&D/H, Caryn Miller <i>Caryn Miller</i>
		Date: 5/3/93
		Date: 4/27/93

18. For the Cooperating Country: The terms and conditions set forth herein are hereby agreed to:  
Signature: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_  
19. For the Agency for International Development:  
Signature: Elizabeth P. Roche, Chief, R&D/PO/PR  
*Elizabeth P. Roche* Title: \_\_\_\_\_ Date: 5/3/93

FOR CONTRACT ACTIONS ONLY: SOURCE SELECTION INFORMATION--SEE FAR 3.104. THIS DOCUMENT, OR PORTIONS THEREOF, CONTAINS PROPRIETARY OR SOURCE SELECTION INFORMATION RELATED TO THE CONDUCT OF A FEDERAL AGENCY ACQUISITION, THE DISCLOSURE OF WHICH IS RESTRICTED BY LAW (41 U.S.C. 423). UNAUTHORIZED DISCLOSURE OF THIS INFORMATION MAY SUBJECT BOTH THE DISCLOSURER AND RECIPIENT TO CONTRACTUAL, CIVIL, AND/OR CRIMINAL PENALTIES AS PROVIDED BY LAW.  
FOR OTHER ACTIONS: UNAUTHORIZED DISCLOSURE OF PROPRIETARY OR SOURCE SELECTION INFORMATION MAY SUBJECT AN EMPLOYEE TO DISCIPLINARY ACTION.

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1. Cooperating Country <b>Worldwide</b>	2. PIO/T No. <b>936-5600</b> <b>3692436A</b>	3. PIO/T Amend No. <b>1</b>
4. Project/Activity No. and Title <b>R&amp;D/R Project 936-5600, Innovative Scientific Research II, Grant 10.211, "Assessment of PCR Predictive Test..."</b>	5. Appropriation Symbol(s) <b>72-1131021.1</b>	
7. Pro Ag No. or Project Authorization Date <b>Action Memo Approved 4/10/90</b>	6. Budget Plan Code(s) <b>DDVA-93-16950-KG-11 (341-36-099-00-19-31)</b>	
9. Project Assistance Completion Date <b>(Month, Day, Year) 12/31/99</b>	8. Obligation Status <input checked="" type="checkbox"/> Administrative Reservation <input type="checkbox"/> Implementing Document	
	10. Authorized Agent <b>FA/OP/A/HRN</b>	

11. Type of Action and Governing A.I.D. Handbook [B]	12. Contract/Grant/Cooperative Agreement/Reference Number (if this PIO/T is for an order or a modification to an award) <b>TBD</b>
A. A.I.D. Contract (HB14) B. A.I.D. Grant or Cooperative Agreement (HB 13)	C. PASA/RSSA (HB 12) D. Other

13. A.I.D. Funding (Attach a detailed budget in support of column (2) as Attachment A.)

	(1) Previous Total	(2) Increase	(3) Decrease	(4) Total to Date
A. Dollars	30,000	74,900		104,900
B. U.S.-Owned Local Currency				0

14. Mission References

15. Instructions to Authorized Agent

Request that you increase the funding of this PIO/T by \$74,900. The purpose of this increase is to fully fund the total amount of the research grant in FY93. A copy of the original PIO/T is attached.

FA/FM/A/NPA & PA  
OFFICE OF FINANCIAL MANAGEMENT  
ACTION: *Reserve*

16. Address of Voucher Paying Office Agency for International Development  
FA/FM/CMP/DC, Room 700, SA-2, Washington, D.C. 20523 RA

17. Clearances - Include typed name, office symbol, and date for all clearances

A. The Project Officer certifies (1) that the specifications in the statement of work or program description are technically adequate, and (2) that (for contract actions only) all program personnel who are defined as procurement officials under 41 U.S.C 423 have signed the Procurement Integrity Certification (OF-333).

Signature R&D/R, Miloslav Rechciol <i>MR</i>	Date: <b>6/15/93</b>	Phone No: <b>5-4444</b>
B. The statement of work or program description lies within the purview of the institution office and approved agency Signature: R&D/R Wayne W. P. Ching Date: <b>6/25/93</b>	C. Signature: R&D/PO/AE, G. Standrod Date: <b>6/25/93</b>	
D. Funds for the services requested are available Signature: FA/FM/A/NPA Rose Anderson Date:	E. <i>for name</i> Signature: R&D/H, Caryn Miller Date: <b>6/25/93</b>	

18. For the Cooperating Country: The terms and conditions set forth herein are hereby agreed to:

Signature: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

19. For the Agency for International Development:  
Signature: *Elizabeth P. Roche* Title: \_\_\_\_\_ Date: **6/30/93**

