

AGREEMENT
between the
AMERICAN INSTITUTE IN TAIWAN
and
THE COORDINATION COUNCIL FOR NORTH
AMERICAN AFFAIRS
for
TECHNICAL COOPERATION
in
VACCINE AND IMMUNIZATION-RELATED ACTIVITIES

I. COORDINATION

This Agreement between The American Institute in Taiwan (AIT) and the Coordination Council for North American Affairs (CCNAA) establishes a framework for the Office of International Health (OIH), Office of the Assistant Secretary for Health, U.S. Public Health Service, as the designee of AIT, to carry out reimbursable technical cooperation with the Department of Health (DOH), Executive Yuan, the designee of CCNAA.

II. OBJECTIVES

The objectives are:

1. To undertake cooperative activities to strengthen the vaccine and immunization program in the territory represented by CCNAA.
2. To provide technical assistance to plan and implement the National Plan of Eradication of Poliomyelitis (polio), Elimination of Measles, Neonatal Tetanus (NNT) and Congenital Rubella Syndrome (CRS).
3. To provide professional development and training for health professionals in the territory represented by CCNAA for vaccine-preventable diseases prevention and control.
4. To provide technical assistance in problem-solving, operations research to ensure the success of the National Plan of eradication of polio and elimination of measles, NNT and CRS.
5. To provide technical assistance in the quality assurance and quality control of vaccines produced or imported into the territory represented by CCNAA.
6. To provide technical assistance to strengthen the laboratory diagnostic capacity to support the vaccine and immunization program in the territory represented by CCNAA.

III. COOPERATIVE ACTIVITIES

Cooperative activities under this agreement may include the following:

1. Providing technical assistance in management and implementation of a plan of disease eradication and elimination including the surveillance system, laboratory diagnostic capacity, immunization coverage, cold chain maintenance, vaccine safety and potency and social mobilization;
2. Conducting joint problem-solving research projects;
3. Exchange of information, scientists and technical experts;
4. Convening seminars and meetings;
5. Training of participants;
6. Conducting joint international workshops/meetings;
7. Monitoring or evaluating program effectiveness;
8. Other forms of cooperation in the areas of vaccine and immunization.

IV. IMPLEMENTATION

1. AIT and CCNAA will conclude implementing arrangements concerning specific cooperative activities to be conducted under this Agreement.
2. Each implementing arrangement shall specify the technical scope of the activities, management responsibilities, specific funding arrangements, cost and schedule estimates, procedures to be followed, treatment of intellectual property, liability, and other appropriate matters.
3. All cooperative activities undertaken pursuant to specific implementing arrangements under this agreement shall be subject to the respective and applicable laws, regulations, policies, funding, and administrative procedures of AIT, and its designated representative, OIH, and CCNAA, and its designated representative, DOH.
4. OIH and DOH may in subsequent years of this Agreement, continue to cooperate on mutually agreed upon activities that are within the scope of services described in the Implementating Arrangement or within the framework of cooperative activities already in the Agreement.

V. FINANCIAL ARRANGEMENTS

1. Activities under this agreement are conducted on a fully reimbursable basis unless other arrangements are specified and mutually agreed to in implementing arrangements to this Agreement.
2. CCNAA shall pay all costs associated with services provided to CCNAA, or its designated representative, DOH, by AIT or its designated representative, OIH, under this agreement.
3. AIT shall provide CCNAA with documentation supporting requests for reimbursement in accordance with standard financial regulations and practices of AIT and its designated representative, OIH.
4. CCNAA shall make all necessary arrangements to reimburse AIT for all actual costs incurred by AIT, or its designated representative, OIH, under this agreement.
5. Each implementing arrangement shall specify funding and payment arrangements and shall include an estimated budget for at least the first year of activity.

VI. RESPONSIBILITIES OF AIT

AIT shall carry out its responsibilities pursuant to this agreement with due diligence and efficiency.

1. AIT shall, through its designated representative, OIH, keep accurate and systematic accounts and records with respect to the services provided pursuant to this agreement in such form and detail as is customary, and shall permit CCNAA, or its designated representative, DOH, to inspect same and make copies thereof.
2. AIT shall, through its designated representative, OIH, furnish to CCNAA, or its designated representative, DOH, such information related to the services AIT shall provide to CCNAA pursuant to this agreement as may be reasonably requested.
3. Upon completion of specific services provided to CCNAA by AIT, as delineated in the implementing arrangements under this agreement, AIT shall deliver to CCNAA, or to its representative, DOH, all reports, calculations, comments, suggestions, and relevant technical data compiled or prepared by AIT, or its designated representative, OIH, in and under this agreement. Such shall become the sole property of CCNAA, or its designated representative, DOH, pursuant to this agreement.
4. To the extent that funds are made available to AIT by CCNAA, AIT, through its designated representative, OIH, will make available such personnel and facilities necessary to carry out activities pursuant to this agreement.

5. AIT, through its designated representative, OIH, shall provide suitably qualified personnel who are acceptable to CCNAA and to CCNAA's designated representative, DOH. Personnel will be selected on merit factors such as education, experience and expertise.
6. AIT, through its designated representative, OIH, shall provide all technical and administrative support and other requirements as may be necessary to complement and supplement the services of personnel of AIT's designated representative, OIH, who are in the territory represented by CCNAA under the auspices of AIT.

VII. RESPONSIBILITIES OF CCNAA

1. Pursuant to this agreement, CCNAA shall assist AIT in obtaining visas and other documents necessary for personnel of AIT's designated representative, OIH, who visit the territory represented by CCNAA under the auspices of AIT in order to carry out this agreement.
2. Pursuant to this agreement, CCNAA shall assist AIT in obtaining the necessary permits and authorizations for carrying out the assistance specified in the implementing arrangements to this agreement, including access to facilities and areas under jurisdiction of CCNAA's designated representative, DOH, by personnel of AIT's designated representative, OIH, who are in the territory represented by CCNAA under the auspices of AIT.
3. CCNAA shall, pursuant to this agreement, assure that AIT, and its designated representative, OIH, are held free and clear of all customs duties and impositions charged by the authorities in the territory represented by CCNAA. Neither AIT nor its designated representative, OIH, shall be required to pay any duties or taxes in executing the terms and conditions of this agreement.

VIII. INTELLECTUAL PROPERTY CONSIDERATIONS

1. AIT, and its designated representative, OIH, and CCNAA, and its designated representative, DOH, support the widest possible dissemination of information provided, exchanged or arising under this agreement, subject to the needs to protect preexisting proprietary information, patent and copyright restrictions.
2. Details concerning intellectual property considerations and information dissemination procedures will be specified in each implementing arrangement to this agreement.
3. Information transmitted by either party to this Agreement to the other party shall be accurate to the best knowledge and belief of the transmitting party but the transmitting party does not warrant

the suitability of the information transmitted for any particular use or application by the receiving party or by any third party.

4. Information developed jointly by the parties shall be accurate to the best knowledge and belief of both parties. Neither party warrants the accuracy of the jointly developed information or its suitability for any particular use or application by either party or by any third party.

IX. LIABILITY

CCNAA shall assist in the defense against any suit brought against the Government of the United States, AIT, AIT's designated representative, OIH or any instrumentality or officer of the United States arising out of the activities associated with this Agreement. CCNAA further agrees to hold the territory represented by AIT, AIT, AIT's designated representative, OIH, or any instrumentality or officer of the United States, harmless against any claim by CCNAA, CCNAA's designated representative, DOH, or any entity or person in the territory represented by CCNAA or elsewhere for personal injury, death or property damage arising out of work performed under this Agreement.

Except for damage to, or destruction of, property of AIT, or its designed representative, OIH, caused by personnel of AIT, or its designated representative, OIH, CCNAA agrees to reimburse AIT, or its designated representative, OIH for any damage or destruction of property belonging to AIT, or its designated representative, OIH, arising out of activities associated with this Agreement.

X. EFFECTIVE DATE

This Agreement will become effective on the date of the last signature hereafter.

XI. AMENDMENT AND TERMINATION

This Agreement, and its Implementing Arrangements, may be amended by the mutual written agreement of AIT and CCNAA.

This Agreement may be terminated by either party at any time by notification to the other party in writing sixty days in advance of the desired termination date. It is understood that an attempt will be made to reach mutual agreement on the termination of activities and repatriation of personnel.

XII. RESOLUTION OF DIFFICULTIES

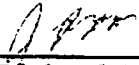
AIT and CCNAA shall consult, upon request of either party, regarding any matter related to the terms of this Agreement, and shall endeavor jointly, in a spirit of cooperation and mutual trust, to resolve any difficulties or misunderstanding that may arise.

IN WITNESS WHEREOF, the undersigned, being duly authorized have signed this Implementing Agreement.

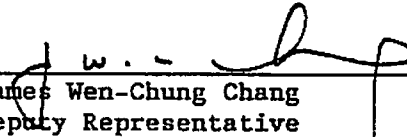
DONE at Washington, D.C., in duplicate, in English language.

FOR THE AMERICAN INSTITUTE
IN TAIWAN

FOR THE COORDINATION COUNCIL
FOR NORTH AMERICAN AFFAIRS



J. Richard Bock
Deputy Managing Director



James Wen-Chung Chang
Deputy Representative

10/6/94
Date

10/7/94
Date

IMPLEMENTING ARRANGEMENT #1

to the

Agreement between AIT and CCNAA for Technical Cooperation in Vaccine and Immunization-related Activities

I. PURPOSE

To evaluate the requirements and specifications for establishing an effective National Plan of Eradication of Polio and Elimination of Measles, Neonatal Tetanus (NNT), and Congenital Rubella Syndrome (CRS) being developed by the DOH. The National Plan includes the surveillance system, laboratory supports, immunization coverage, provision of safe and effective vaccines and epidemiological investigation system, social mobilization and research efforts.

The activities described in this Implementing Arrangement will be carried out under the general terms and conditions established by the Agreement between AIT and CCNAA in the Technical Cooperation in Vaccine and Immunization-Related Activities. This Implementing Arrangement is hereby attached to that Agreement and becomes part of the Agreement.

II. SERVICES

1. Arrange training programs for scientists and health professionals in the territory represented by CCNAA in disease surveillance, outbreak investigation, laboratory diagnostics and vaccine quality control.
2. Arrange one or two technical workshops a year to provide a state-of-the-art knowledge in vaccine and immunization-related activities.
3. Provide technical assistance in assessment of the feasibility of establishing a surveillance system for monitoring vaccine adverse events.
4. Provide technical assistance in the area of vaccine compensation program in the territory represented by CCNAA.
5. Provide support for laboratory diagnostic services including assay standardization, access to reference reagents, establishing a reference laboratory capacity and laboratory surveillance system in the territory represented by CCNAA with particular emphasis on the poliomyelitis eradication.

6. Provide periodic consultation on the progress of the implementation of the National Plan of disease eradication and elimination.

III. IMPLEMENTATION PLAN FOR YEAR 1

1. Participate in the biannual review of the progress of the National Plan of Eradication of Polio, Elimination of Measles, NNT, and CRS. The OIH team will identify areas that need assistance and recommend measures to improve the effectiveness of the program implementation.

Two person team x 2 trips/year @ 2 weeks/trip

2. Conduct an overall evaluation of cold chain maintenance systems for vaccines both in the public and the private sectors.

The OIH will identify a cold chain specialist to review the cold chain systems including site visits, identify the strengths and weaknesses of the system, specify training needs and recommend actions as needed.

One person, one trip @ 2 weeks

3. Provide training to all levels of cold chain maintenance personnel in the territory represented by CCNAA.

One person, one trip @ 2 weeks

4. Review the adequacy of laboratory diagnostic capacity both in the DOH and the field in support of polio eradication and elimination of measles and CRS, identify the training needs and provide laboratory services for polio virus characterization such as intratypic differentiation of polio virus strain.

One/two persons, two trips each @ 2 weeks/trip

Intratypic differentiation of polio virus estimated 50 strains/year

5. Conduct a workshop on the National Plan of Disease Eradication and Elimination for the medical community with particular emphasis on surveillance and case investigation. The purpose of the workshop is to inform the medical community of the National Plan and its implementation efforts and to increase overall awareness of polio eradication, and elimination of measles, NNT and CRS Programs.

Two persons, one trip each @ 1 week

6. Conduct special studies in collaboration with appropriate investigation in the territory represented by CCNAA in support of the National Plan of Polio Eradication and Elimination of Measles, NNT and CRS.

The U.S. collaborators will make 3 site visits for the following activities:

- 6.1 Rapid assessment of the serological response to three doses of trivalent oral polio vaccine.

The purpose of this study is to obtain data on the serological response to 3 doses of trivalent opv in children less than one year of age when administered under actual field conditions.

- 6.2 Monitoring of vaccine potency in the field.

The purpose of this study is to compare the vaccine potency at the time of purchase and the time to administer and to measure the potency loss during transportation and storage.

- 6.3 Retrospective case ascertainment of polio, NNT, CRS, and hospitalized measles cases.

Using hospital discharge records, this study will identify cases of polio, NNT, CRS, and measles that were admitted to major teaching hospitals in the past 10 years and provide data to design a prospective hospital-based surveillance for the eradication efforts.

IV. FINANCIAL ARRANGEMENTS

1. The total cost for activity described in the Implementation Plan for Year One of this Implementing Arrangement # 1 is mutually agreed not to exceed U.S. \$100,000.
2. DOH will observe the per diem rates specified in a regulation promulgated by the Executive Yuan on December 14, 1991, which states that visiting lecturers from abroad should be paid NTD 6,000.00 per day for their living expenses.
3. Salary compensation for personnel sent to the territory represented by CCNAA for a period exceeding three weeks may be discussed on a case by case basis.

V. INTELLECTUAL PROPERTY CONSIDERATIONS

There are no intellectual property rights (IPR) expected to arise in conjunction with activities described in this Implementing Arrangement. CCNAA is requesting AIT expertise and knowledge to develop a National Vaccine Plan for polio eradication and elimination of measles, NNT, and CRS. The objective of the cooperative activities is to strengthen vaccine and immunization-related activities in the territory represented by CCNAA. Although reference reagents may be provided, only products that are in routine use in the territory represented by AIT and WHO's Expanded Programme for Immunization (EPI) will be used. Any testing of vaccines will be subject to internationally recognized standard procedures applied to vaccine research. All activities are nonpatentable.

The annual Implementation Plan will not be distributed to other parties until it has been approved in final form by AIT, and its designated representative, OIH and CCNAA, and its designated representative, DOH.

VI. EFFECTIVE DATE

This Implementing Arrangement is effective on the date of the last signature hereafter.

VII. AMENDMENT AND TERMINATION


This Implementing Arrangement may be amended or terminated in accordance with the terms of the Agreement.

IN WITNESS WHEREOF, the undersigned, being duly authorized have signed this Implementing Arrangement.

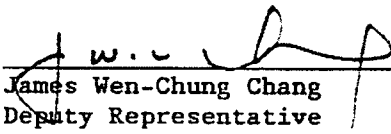
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