

MAINTENANCE AND EXAMINATION OF RECORDS CLAUSE

(a) The Organization agrees to keep records adequate for documentation of the progress made in and the status of the contract as well as for the preparation of reports on the scientific aspects thereof. The organization further agrees to maintain separate records of funds received, obligations incurred, and actual expenditures, in carrying out the contract.

(b) Until the expiration of three years after final payment under this contract, at any reasonable time, accredited representatives of the Department of Health and Human Services (DHHS) and the General Accounting Office (GAO) will have access to that part of the research facilities or offices utilized in connection with the contract, as well as to any directly pertinent books, documents, papers or records of the Organization involving transactions related to this contract. DHHS and GAO representatives may copy such of these materials as they deem necessary. Officers of the organization or other personnel assigned to or engaged in the conduct of this project shall be available for consultation with DHHS or GAO at any reasonable time during the time records may be accessed.

(c) The Organization shall provide data as stated in paragraph (b) above except for any items of data which may be protected from disclosure under separate written agreements between the Organization and a third party. However, the Organization will make every reasonable effort to obtain concurrence from the third party to provide such protected data. In any instance when concurrence cannot be obtained, the Organization agrees to make available the information, deleting only those portions considered to be confidential to third parties.

(d) The Organization will further endeavor to include in all its subcontracts hereunder, a provision to the effect that the subcontractor agrees to make available to the Comptroller General of the United States or any of his duly authorized representatives, until the expiration of three years after final payment under the subcontract, any directly pertinent books, documents, papers, and records of such subcontractor involving transactions related to the subcontract, and allow the copying of such contractor materials as the Comptroller General or his duly authorized representatives deem necessary. The term "subcontract" as used in this clause excludes (1) purchase orders not exceeding \$10,000 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(e) Without prejudice to paragraph (b) and the performance and reporting of audits inherent therein, the specific contract will be subject exclusively to the internal and external auditing procedures laid down in the financial rules, regulations, and directives of the Organization.

Department of Health and Human Services

Determination and Findings

Authority to waive the requirement for application of the "Examination of Records by the Comptroller General" clause for contracts with the World Health Organization (WHO) and its subsidiary, the Pan American Health Organization (PAHO), pursuant to Subpart 25.903(a)(1) of the Federal Acquisition Regulation (FAR), for a 3-year period.

I hereby find that:

(1) The Public Health Service (PHS), on behalf of the Department of Health and Human Services (HHS), proposes to enter into approximately two new contracts with WHO and one contract with PAHO in the current year and in each of the two succeeding years. These contracts will contribute to the missions of WHO/PAHO, PHS, and HHS, in helping to improve the health of the citizens of the United States and all other nations of the world. In most, if not all, of these contracts, WHO/PAHO is in a unique position as an international nonprofit organization to carry out important and beneficial programs requiring the cooperation of numerous nations. The inability to enter into and perform these contract projects would be detrimental to the public interest of both the United States and other nations.

These contracts are more specifically as follows:

1. International Epidemiologic Studies of Occupational and Environmental Cancer - This project is a series of collaborative, international investigations of occupational and environmental cancer.
2. Caribbean Epidemiology Centre/PAHO - This project will evaluate human retroviruses in the Caribbean Basin, with particular focus on HTLV-I and HTLV-III. The focus of this project is on the epidemiology of the viruses in Trinidad and in the region as well as investigations of diseases associated with this infection.
3. Prevention of Disease Caused by Smoking - This contract will provide support of WHO in health education activities worldwide.

(2) WHO/PAHO, however, is unwilling to enter into any proposed contract which incorporates the "Examination of Records by the Comptroller General" clause set forth in FAR 52.215-1 or any clause which provides access to or the right to examine the books, documents, papers, records or financial accounts of WHO involving transactions whether or not related to a specific contract. Extensive discussions were held with

representatives of the WHO/PAHO in Bethesda, Maryland on February 16 and 17, 1982 intending to result in a Basic Agreement for application to contract awards to the WHO/PAHO. It was made clear that use of the "Examination of Records by the Comptroller General" clause in contract awards to WHO/PAHO is: (a) contrary to the Financial Regulations of the WHO/PAHO; (b) not required by the laws of the United States of America; and (c) not acceptable to WHO/PAHO nor the United States of America as a member of the World Health Assembly.

(3) The contractor's reasons for refusal to include the clause are set forth in summary form as follows:

(a) To accept a contract containing such a clause would be a direct violation of the Financial Regulations of WHO/PAHO adopted by the Fourth World Health Assembly (as subsequently amended).

(b) The United States of America, a member nation of the World Health Assembly, has by Executive Order 10025 designated WHO/PAHO as a Public International Organization allowed to enjoy the privileges, exemptions, and immunities conferred by the International Organizations Immunities Act (Public Law 291-79th Congress; 59 Stat. 669), thereby exempting WHO/PAHO from the laws of the United States of America.

(c) The United States of America, as a member of the World Health Assembly, has accepted the premise that no member Government may have special access to the financial records of WHO/PAHO; the United States of America, as a sovereign nation, has waived any claim of sovereignty over WHO/PAHO.

(4) In most cases, the services sought under the proposed contracts to WHO/PAHO are not available from other sources within or outside the United States. Often, epidemiological research services are required which are not available from any other source because no other organization is in a position to identify which countries and geographic localities should be selected for study to provide a valid representation and to cover the wide range of risk factor/event relationships that are needed to provide meaningful information.

WHO/PAHO possesses established relationships with the Governments of other countries which permit access to the health care facilities at which patient data would be gathered. WHO/PAHO also has equal stature with other Governments, by international treaty and possesses the necessary international channels of communication to permit maintaining contact with research subjects who may move from one country to another.



**Comptroller General
of the United States**

Washington, D.C. 20548

B-101404.2

May 16, 1989

The Honorable Ralph R. Reed, M.D.
Acting Assistant Secretary for Health
Department of Health & Human Services

Dear Dr. Reed:

Your March 29, 1989, letter requests my concurrence with your determination that the "Examination of Records by Comptroller General" clause be omitted from a class of proposed Public Health Service contracts with the World Health Organization (WHO) and the Pan American Health Organization (PAHO) for a 3-year period. In lieu of the standard clause, the proposed contracts would contain the "Maintenance and Examination of Records" clause attached to your letter. On December 31, 1985, this Office approved the use of the same alternate clause in all WHO contracts entered into for the next 3 years, during which time the impact of the clause would be assessed.

Your submission indicates that the proposed contracts with the two organizations will be for epidemiological research services that generally are not available from other sources within or outside the United States. You state that the inability to enter into and perform the contracts would be detrimental to the interests of both the United States and other nations. You also suggest that other controls exist, through the WHO/PAHO financial system and procedures, and through the World Health Assembly audit process, to ensure that money is properly spent, reimbursed and accounted for.

In view of the above, and since the language of the proposed substitute clause is identical to that previously approved for use in WHO contracts, I concur with your decision to

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omit the "Examination of Records by Comptroller General" clause and substitute therefor the "Maintenance and Examination of Records" clause in the contracts and for the period proposed.

Sincerely yours,

Milton J. Fowler

Acting Comptroller General
of the United States