

Memorandum of Understanding
between the Ministry of Health of the Italian Republic
and the U.S. Department of Health and Human Services
on Health and Medical Sciences

The Ministry of Health of the Italian Republic and the U.S. Department of Health and Human Services (HHS): guided by the willingness to develop fruitful cooperation between their respective countries in the field of health and medical sciences; and considering the importance of international cooperation to ensure an enhanced focus on bioterrorism, oncology, rare diseases, and other important health issues; and considering that the United States and Italy share strong traditions in medical and health research, and have a long history of health collaboration, have reached the following understandings:

Article I

The Ministry of Health of the Italian Republic and the U.S. Department of Health and Human Services, hereinafter referred to as the Participants, intend to enhance and expand cooperative efforts in health and medical sciences according to the following general principles:

All activities are to be conducted on the basis of equality, reciprocity and mutual benefits.

The cooperation provided for in this Memorandum does not affect relations currently established between institutions or individuals of the United States of America and the Italian Republic. Rather, the Participants intend to attempt to identify new areas for joint activities and to avoid unnecessary duplication.

Joint activities, where possible, are expected to be coordinated with, or be supportive of, the activities and goals of other international health bodies, including the World Health Organization and the United Nations family of organizations.

Article II

The Participants plan to provide for an expansion of cooperation across a broad range of mutual interests. Initial efforts are to be directed at developing joint activities addressing their common problems in the areas of:

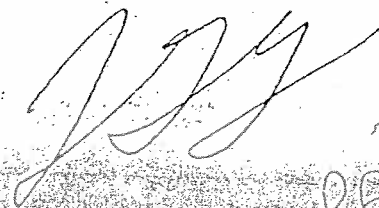
- Bioterrorism;
- Oncology; and
- Rare diseases.

Other specific areas may be identified from time to time by mutual consent of the Participants or their designees.

Article III

The methods of cooperation provided for in this Memorandum include, but are not limited to:

- Exchange of scientists, delegations, information and technology;
- Organization of meetings and scientific conferences; and
- Coordinated scientific programs and research projects.



The Participants also intend to encourage and facilitate the establishment of direct relationships between other appropriate institutions and individuals in the two countries.

Article IV

For each area of cooperation, and initially for those areas identified in Article II, the Participants or their designees intend to identify an appropriate entity to take the lead in overseeing the practical implementation of activities. The appropriate entity should be responsible for coordinating communications and activities with his counterpart and should be responsible for fulfilling mutually decided responsibilities. The components of HHS currently involved under this Memorandum include: the Office of the Assistant Secretary for Public Health Emergency Preparedness; the National Institutes of Health; and the Food and Drug Administration. The Italian components currently involved under this Memorandum include: the Istituto Superiore di Sanità (NIH), the Istituto Lazzaro Spallanzani and the Ospedale Luigi Sacco (Institutes for Infectious Diseases), the Istituto CSS Mendel (Institute for Genetic Diseases), and the Alleanza contro il Cancro (Cancer Hospital Network).

The Special Assistant to the Secretary for International Affairs, in the Office of the Secretary, HHS, is designated as being responsible for fulfilling the terms of this Memorandum within the purview of the U.S. Department of Health and Human Services. The Director General of International Affairs, Ministry of Health, is designated as being responsible for fulfilling the terms of this Memorandum within the purview of the Republic of Italy.

Article V

All activities undertaken pursuant to this Memorandum are to be conducted in accordance with the laws and regulations of both countries and are subject to the availability of personnel, resources, and appropriated funds. Steps for implementing this Memorandum are to be developed through mutual consultations following signature of this Memorandum of Understanding.

Article VI

Activities under this Memorandum commence upon signature by both Participants for a period of five years. This Memorandum may be amended or extended by the mutual written decision of the Participants.

This Memorandum supersedes the Memorandum of Understanding between the U.S. Department of Health, Education and Welfare and the Ministry of Health of the Italian Republic, which was signed in Rome on November 21, 1977.

DONE at Rome, in duplicate, this seventeenth day of April 2003, in the English and Italian languages.

FOR THE MINISTRY OF HEALTH OF THE
ITALIAN REPUBLIC :



FOR THE U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES:

Technical Annex
to the
Memorandum of Understanding

between the U.S. Department of Health and Human Services (HHS)
and the Ministry of Health of the Italian Republic
on Health and Medical Sciences

HHS Secretary Tommy Thompson and Minister Girolamo Sirchia met in Washington, D.C., June 23, 2003, to review progress made in implementing the Memorandum of Understanding (MOU) on health and medical sciences signed in Rome, Italy on April 17, 2003.

They noted that U.S. and Italian experts met during the seventh biennial review of the U.S.-Italian Agreement on Scientific and Technological Cooperation, June 17-18, 2003, to further define work programs pursuant to the implementation of the Memorandum. The experts concurred on the following elaborations of topics included in Article II of the Memorandum.

Bioterrorism – the U.S. and Italian health experts have decided to strengthen collaboration on innovative diagnostic tools, prophylactic vaccines and treatments. In addition, both sides will work together to identify and implement the most effective infectious disease prevention and control measures. Priority should be given to dangerous pathogens implicated in bioterrorism, e.g. smallpox and anthrax, and emerging and reemerging infections. Cooperation may include: scientist exchanges; workshops to share results and experiences; sharing of information, materials and reagents; and training programs for researchers and technicians.

Oncology – Minister Girolamo Sirchia and Dr. Andrew von Eschenbach, Director, U.S. National Cancer Institute, met in Milan on June 16, 2003, and decided that a part of the U.S.-Italian cooperation should focus on pharmacogenomics. The next step is a bilateral meeting between U.S. and Italian experts to identify specific research topics. Other cooperation under this topic is to be discussed in Italy the week of June 23, 2003, and once decided upon by the two ministries, should be incorporated into this Technical Annex by reference.

Rare Diseases – the U.S. and Italian specialists identified three categories of rare diseases as priorities: neurodegenerative disorders; metabolic diseases; and, small chromosomal rearrangements such as microdeletions and duplication. They also decided on several general goals: improve diagnosis and detection of rare diseases and conditions; improve availability of patient services and information on rare diseases and conditions; and increase patient and health care provider access to and participation in clinical trials and other research projects on rare diseases. Collaboration among companies in both countries involved in research and development as well as in the manufacture of orphan drugs will also be encouraged.

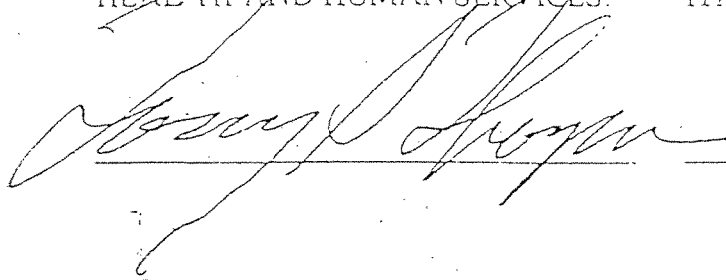
The two Ministers reviewed and endorsed the proposals outlined above and decided that these specific collaborations should be pursued in the areas delineated in accordance with Article V of the Memorandum.

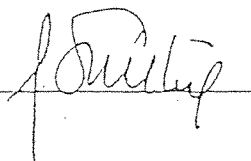
The activities under this Technical Annex will be conducted subject to the laws, policies, and regulations and the availability of funds and other resources of the host and sponsoring countries. Each side will cover the international airfare and subsistence costs of its participants. With respect to joint projects, the two sides will work together to identify project costs as collaborative projects are developed. The U.S. side welcomed the Italian statement that the following amounts have been identified by the Italian side for the three topical areas: oncology \$10 million; rare diseases \$5 million; and, bioterrorism preparedness \$2.5 million.

Done in Washington, D.C., in duplicate, this twenty-third day of June 2003 in the English language.

FOR THE U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES:

FOR THE MINISTRY OF HEALTH OF THE
ITALIAN REPUBLIC:





Addendum
al
Memorandum di Intesa
tra
il Ministero della Salute della Repubblica Italiana
e
il Dipartimento della Sanità e dei Servizi Umani degli
Stati Uniti d'America
nel campo della sanità e delle scienze mediche

Il Ministero della Salute della Repubblica Italiana ed il Dipartimento della Sanità e dei Servizi Umani degli Stati Uniti d'America, guidati dall'intento di sviluppare una fruttuosa collaborazione fra i loro rispettivi Paesi nel campo della sanità e delle scienze mediche; e considerando l'importanza della collaborazione internazionale per assicurare una maggiore concentrazione sulle materie principali pertinenti alla sanità; e considerando che gli Stati Uniti d'America e l'Italia condividono forti tradizioni nel settore della ricerca medica e sanitaria ed hanno una lunga consuetudine di collaborazione nel campo della sanità – tenendo conto del Memorandum di Intesa (Memorandum of Understanding = MOU) firmato a Roma in data 17 aprile 2003 dai Partecipanti, e dall'Allegato tecnico (Technical Annex) firmato a Washington, D.C. in data 23 giugno 2003 dai Partecipanti – hanno deciso di mutuo accordo di aggiungere altre aree specifiche a quelle già identificate per la loro priorità in Articolo II del Memorandum di Intesa, ed hanno raggiunto la seguente intesa:

In Articolo II del già citato Memorandum di Intesa, dopo le parole "Malattie rare" ("Rare Diseases"), vanno aggiunte le seguenti aree di cooperazione:

- Cellule staminali adulte
- Epidemiologia e prevenzione delle principali cause di mortalità
- Trapianti di organi, trapianti e terapie cellulari
- Preparazione per venire incontro alla lotta contro l'influenza aviaria e pandemica

SOTTOSCRITTO a Roma, in duplice copia in lingua inglese ed italiana, addì diciassette novembre 2005.

PER IL
MINISTERO DELLA SANITÀ DELLA
REPUBBLICA ITALIANA



PER IL
DIPARTIMENTO DELLA SANITÀ
E DEI SERVIZI UMANI DEGLI
STATI UNITI D'AMERICA

