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John O'Neil . . . 9/15

~~Attenders~~
~~John~~ No problem.
This is a proposed agreement
w/ Russia for cooperation
in health & biomedical
research. There is no
problem with it but will
not clear until you
approve it. Thank you,
John

Document Originally
Attached to
Following Page



United States Department of State

Bureau of Oceans and International
Environmental and Scientific Affairs

Washington, D.C. 20520

Cleared
15 Sep 92
JFO

September 1, 1992

MEMORANDUM

TO: Distribution

FROM: OES/SCT - Andrew W. Reynolds, Acting

SUBJECT: Request for Circular 175 Authority to Negotiate and Conclude a Memorandum of Understanding Between the Department of Health and Human Services of the United States of America and the Ministry of Health of the Russian Federation for Cooperation in the Field of Health and Biomedical Research.

The Department of Health and Human Services has requested Circular 175 authority to negotiate and conclude the subject Memorandum of Understanding (MOU) with the Russian Federation Ministry of Health. A copy of the proposed MOU is attached.

Please provide your comments and clearance to Cathleen Campbell, 647-4662 (phone) and 647-0773 (fax), no later than COB September 15, 1992. If there is a problem meeting this deadline, please advise immediately; your clearance will be assumed if you have not responded by that time.

Thank you for your assistance in this matter.

Attachment:
As stated.

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MEMORANDUM

TO: OES - Mr. Bohlen

THROUGH: OES/S - Dr. Boright

FROM: OES/SCT - Martin Prochnik

SUBJECT: Request for Circular 175 Authority to Negotiate and Conclude a Memorandum of Understanding in the Field of Health and Biomedical Research between the United States Department of Health and Human Services and the Russian Federation Ministry of Health.

ISSUE FOR DECISION

Whether to grant Circular 175 authority to negotiate and conclude the subject Memorandum of Understanding (MOU) between the Department of Health and Human Services (DHHS) and the Russian Federation Ministry of Health.

DESCRIPTION OF THE AGREEMENT

Purpose: The fundamental purpose of this cooperation is to prevent the spread of disease, improve health, and conduct mutually beneficial collaborative research on a range of health related issues to include basic biomedical research, clinical care research, health services and health policy research, statistics, and exchange of regulatory and standard setting activities pertaining to biologics, pharmaceuticals and medical devices.

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Background: For twenty years, the U.S. Department of Health and Human Services has had an active program of scientific cooperation with major All-Union Centers and Research institutions under the Ministry of Health of the former Soviet Union. The Russian Federation Ministry of Health has been named and recognized by the U.S. as the successor State and organization for the former All-Union Ministry of Health. This agreement is intended to continue provisions which facilitate direct cooperation and collaboration between the U.S. and Russia in the field of Health and Biomedical Research. These provisions address technology transfer requirements, customs and visa assistance, the protection of intellectual property rights and the protection of human subjects and of animals involved in any research.

The previous Joint Health Committee structure has been dropped in favor of simply naming two executive agents, one for each side. On the U.S. side, this will rest with the Deputy Assistant Secretary for International Health, who is charged with developing appropriate program and administrative guidance to DHHS participants.

At the last meeting of the US-USSR Joint Health Committee, June 18-20, 1992, progress in six areas of cooperation was reviewed and ten new areas were added. These areas continue to be of high interest in development of a new agreement between the U.S. and Russia.

Cooperation in the past has involved such topics as epidemiology on cardiovascular disease risk factors, clinical trials on drugs for treating cancer, arthritis, and hepatitis, as well as exchange of influenza virus sample for making U.S. flu vaccines. These areas of interest are expected to continue along with additional emphasis on such important areas as adverse health effects posed by radiation exposure and environmental pollution. In many cases, through cooperative research, U.S. scientists gain access to data and information that otherwise would be very costly or impossible to obtain in the U.S.

SOURCE OF FUNDING

In general, DHHS plans to follow its long-established pattern for this region of the world in which each side is responsible for paying for the costs of sending its personnel to the other country (sending side pays for international travel) and the receiving side pays for incountry costs. This will be applied with flexibility, given the current financial situation in Russia. Costs to DHHS will be borne out of existing DHHS budgets.

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Activities under this Memorandum are subject to the availability of appropriated funds and personnel. The Department of State commits no funds or personnel to the implementation of this MOU.

ENVIRONMENTAL CONSIDERATIONS

Activities under the proposed MOU will not have adverse or significant effect on the environment outside the United States, and consequently the preparation of an environmental document under E.O. 12114 (January 4, 1979), "Environmental Effects Abroad of Major Federal Actions" is not required.

CONGRESSIONAL CONSULTATIONS

H, OES, and DHHS have determined that no Congressional consultations are necessary due to the routine and technical nature of this type of MOU.

INTELLECTUAL PROPERTY RIGHTS

Article VIII of the MOU provides for the adequate and effective protection and allocation of intellectual property created or furnished under this MOU and relevant implementing agreements.

LEGAL AUTHORITY

On September 18, 1981, pursuant to Circular 175 procedures, the Under Secretary for Security Assistance, Science and Technology reconfirmed the authority of OES to approve the negotiation and conclusion of routine S & T agreements with other governments, subject to approval of the final texts by the appropriate regional bureau and L. Legal authority to negotiate and conclude this agreement is derived from the President's Constitutional powers (Article II) and his authority to represent the nation in foreign affairs, as exercised by the Secretary of State on a day-to-day basis (22 U.S.C. Section 2656). Additional authority is contained in 22 U.S.C. 2656d, which states that "the Secretary of State ...shall have primary responsibility for coordination and oversight with respect to all major science or science and technology agreements and activities between the United States and foreign countries."

DHHS derives its authority to enter into this international agreement from Section 301 and 307 of the U.S. Public Health Service Act (42 USC 241 and 242L).

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RECOMMENDATION

That you grant Circular 175 Authority for the negotiation and conclusion of the proposed MOU subject to the concurrence of OES, EUR, L and other bureaus and agencies, as appropriate, to any changes to the proposed text.

Approve:_____ Disapprove:_____

Date:_____

Attachments:

Tab 1 - Proposed MOU

Tab 2 - Memorandum to Under Secretary Wisner

**MEMORANDUM OF UNDERSTANDING
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA
AND THE MINISTRY OF HEALTH OF THE
RUSSIAN FEDERATION
FOR COOPERATION IN FIELD OF HEALTH AND BIOMEDICAL RESEARCH**

The Department of Health and Human Services of the Government of the United States of America and Ministry of Health of the Government of the Russian Federation (hereinafter "the Parties");

Realizing the importance of progress in the health sciences and health administration for the quality of life for all people;

Desiring to fully share advances in the field of health of benefit to the people of both countries;

Desiring to continue strengthening the friendly relations existing between the peoples of the two countries; and

Recognizing the benefits to be derived by both Parties from close cooperation in these fields,

Have agreed as follows:

ARTICLE I

1. The Parties shall promote cooperation between the two countries in: disease control and prevention, public health protection, biomedical research, health services and health policy research, and health administration and finance.
2. The principal objectives of this cooperation are to provide opportunities to exchange ideas, information, skills and techniques, and to collaborate on problems of mutual interest.

ARTICLE II

The cooperation contemplated in this Agreement may include exchanges of scientific, technical, and health systems management information, exchanges of scientists and technical experts, the convening of joint seminars and meetings, the conduct of joint research projects and other forms of health-related scientific and technical cooperation as may be mutually agreed.

ARTICLE III

Pursuant to the aims of this Agreement, the Parties shall encourage and facilitate, where appropriate, the development of direct contacts and cooperation between constituent agencies and scientists of the two Parties, universities, research centers and other institutions of the two countries.

ARTICLE IV

1. Joint activities, where possible, will be coordinated with, or be supportive of, the activities and goals of international health bodies, including the World Health Organization.
2. Scientists, technical experts, governmental agencies and institutions of third countries or international organizations may, in appropriate cases, be invited by agreement of the Parties to participate, at their own expense unless otherwise agreed, in projects and programs being carried out pursuant to this Agreement.

ARTICLE V

1. To assist in the coordination of activities, to facilitate cooperation, and to provide guidance as needed, the Parties designate the following "Executive Agents" for Each Side:

For the U.S. Department of Health & Human Services:

The Deputy Assistant Secretary for International Health
Office of the Assistant Secretary for Health
U.S. Public Health Service
Room 18-87, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Tel. (301) 443-1774 Fax: (301) 443-0742
Telex: 4900003254 oih ui

For the Ministry of Health of Russian Republic

Foreign Affairs Section
Russian Ministry of Health
3 Rakhmanovsky per.
Moscow, 101431
Tel. 011-70-95 - 928-2442, 921-4672, 292-4217
Fax: 011-70-95 - 927-2805

2. Cooperative activities under this Agreement shall be conducted in accordance with all applicable laws and regulations in both countries and are subject to the availability of funds and personnel.
3. Each organization undertaking cooperative activities and scientific collaboration pursuant to this Memorandum of Understanding shall be responsible for its own costs for its activities, unless otherwise mutually agreed upon in writing. For official visits under this Memorandum, unless otherwise agreed upon, in writing, insofar as possible, the host organization shall provide for, or cover the costs of, transportation, lodging, and per diem, within the borders of its own country, and the sending side is responsible for international air fare.
4. The activities to be carried out under this Memorandum of Understanding may be proposed by either side and shall be documented in work plans or other correspondence, establishing mutual written agreement, in advance of each activity.

5. Protection of Human Subjects -- Before any project involving human subjects is initiated, the Executive Agents identified in Article 5, 1., above, shall be responsible for ensuring full compliance with an international code recognized by both countries, such as the Helsinki Accord (as updated). The Executive Agents are responsible for identifying the pertinent laws and regulations of both countries and for ensuring that any project or activity carried out under this Memorandum of Understanding and involving human subjects shall be in full compliance.
6. Protection of Laboratory Animals and Endangered Species -- The Executive Agents shall be responsible for assuring full compliance with CIOMS International Guiding Principles for Biomedical Research Involving Animals. Before any project or activity carried out under this Memorandum of Understanding and involving animals is initiated, both Parties shall comply with all laws and regulations applicable to the use of laboratory animals. In addition, both Parties shall abide by the Provisions of the Convention on International Trade in Endangered Species.

ARTICLE VI

1. Both Parties agree that no information or equipment identified as requiring protection for national security reasons (such as that which is classified) by either Party shall be provided under this Agreement. Should such information or equipment unintentionally be created or furnished in the course of projects or cooperation under this Agreement, it shall be protected from unauthorized disclosure under applicable laws, regulations and administrative practices. Where information or equipment has been inadvertently disclosed to unauthorized recipients, the originating Party shall be informed.

2. This Agreement does not supersede the international obligations, national laws and regulations of each party with respect to transfers and release of information and equipment subject to export and re-export laws and regulations.

ARTICLE VII

1. Each Party shall use its best efforts to facilitate entry to and exit from its territory of personnel and equipment of the other Party, engaged in or used in projects and programs under this Agreement.
2. Each Party shall endeavor to ensure that all participants in agreed cooperative activities under this Agreement have access to facilities and personnel within its country as needed to carry out those activities.

ARTICLE VIII

The treatment of intellectual property created or furnished in the course of the cooperative activities under this Agreement is set forth in Annex I, which is an integral part of this Agreement.

ARTICLE IX

Nothing in this Agreement shall be construed to prejudice, limit, or determine other arrangements in scientific and technical cooperation or assistance between the two Parties.

ARTICLE X

1. This Agreement shall enter into force upon signature and shall remain in force for five years. It may be amended or extended by mutual agreement of the Parties.

2. The termination of this Agreement shall not affect the validity or duration of any arrangements made utilizing its provisions.

Done at _____, in duplicate, in the English and Russian languages, both texts being equally authentic, this ____ (Date) ____.

FOR THE GOVERNMENT OF THE
UNITED STATES OF AMERICA:

FOR THE GOVERNMENT OF THE
RUSSIAN FEDERATION

(Verbatim copy of Dept. of Commerce IPR Language proposed for US-Russian S&T Agreement, 4/9/92)

ANNEX I
INTELLECTUAL PROPERTY

Pursuant to Article VIII of this Agreement:

The Parties shall ensure adequate and effective protection of intellectual property created or furnished under this Agreement and relevant implementing arrangements. The Parties agree to notify one another in a timely fashion of any inventions or copyrighted works arising under this Agreement and to seek protection for such intellectual property in a timely fashion. Rights to such intellectual property shall be allocated as provided in this Annex.

I. SCOPE

- A. This Annex is applicable to all cooperative activities undertaken pursuant to this Agreement, except as otherwise specifically agreed by the Parties or their designees.
- B. For purposes of this Agreement, "intellectual property" shall have the meaning found in Article 2 of the Convention Establishing the World Intellectual Property Organization, done at Stockholm, July 14, 1967.
- C. This Annex addresses the allocation of rights, interests, and royalties between the Parties. Each Party shall ensure that the other Party can obtain the rights to intellectual property allocated in accordance with this Annex, by obtaining those rights from its own participants through contracts or other legal means, if necessary. This Annex does not otherwise alter or prejudice the allocation between a Party and its nationals, which shall be determined by that Party's laws and practices.
- D. Disputes concerning intellectual property arising under this Agreement should be resolved through discussions between the concerned participating institutions or, if necessary, the Parties or their designees. Upon mutual agreement of the Parties, a dispute shall be submitted to an arbitral tribunal for binding arbitration in accordance with the applicable rules or international law. Unless the Parties or their designees agree otherwise in writing, the arbitration rules of UNCITRAL shall govern.
- E. Termination or expiration of this Agreement shall not affect rights or obligation under this Annex.

II. ALLOCATION OF RIGHTS

- A. Each Party shall be entitled to a non-exclusive, irrevocable, royalty-free license in all countries to translate, reproduce, and publicly distribute scientific and technical journal articles, reports, and books directly arising from cooperation under this Agreement. All publicly distributed copies of a copyrighted work prepared under this provision shall indicate the names of the authors of the work unless an author explicitly declines to be named.
- B. Rights to all forms of intellectual property, other than those rights described in Section IIA above, shall be allocated as follows:
1. Visiting researchers, for example, scientists visiting primarily in furtherance of their education, shall receive intellectual property rights under the policies of the host institution. In addition, each visiting researcher named as an inventor shall be entitled to a share in a portion of any royalties earned by the host institution from the licensing of such intellectual property.
 2. (a) For intellectual property created during joint research, for example, when the Parties, participating institutions, or participating personnel have agreed in advance on the scope of work, each Party shall be entitled to obtain all rights and interests in its own territory. Rights and interests in third countries will be determined in implementing arrangements. If research is not designated as "joint research" in the relevant implementing arrangement, rights to intellectual property arising from the research will be allocated in accordance with paragraph IIB1. In addition, each person named as an inventor shall be entitled to share in a portion of any royalties earned by either institution from the licensing of the property.
 - (b) Notwithstanding paragraph IIB2(a), if a type of intellectual property is available under the laws of one Party but not the other Party, the Party whose laws provide for this type of protection shall be entitled to all rights and interests worldwide. Persons named as inventors of the property shall nonetheless be entitled to royalties as provided in paragraph IIB2(a).

III. BUSINESS-CONFIDENTIAL INFORMATION

In the event that information identified in a timely fashion as business-confidential is furnished or created under the Agreement, each Party and its participants shall protect such information in accordance with applicable laws, regulations, and administrative practices. Information may be identified as "business-confidential" if a person having the information may derive an economic benefit from it or may obtain a competitive advantage over those who do not have it, the information is not generally known or publicly available from other sources, and the owner has not previously made the information available without imposing in a timely manner an obligation to keep it confidential.

OIH DRAFT 8/21/92 on G:\bilat\eeuro\ "RUSMOUC2.175"