SCIENTIFIC AND TECHNICAL COOPERATION

Health Research

Agreement Between the
UNITED STATES OF AMERICA
and UGANDA

Signed at Kampala May 9, 2017
Entered into force May 9, 2017

NOTE BY THE DEPARTMENT OF STATE

Pursuant to Public Law 89—497, approved July 8, 1966 (80 Stat. 271; 1 U.S.C. 113)—

". . .the Treaties and Other International Acts Series issued under the authority of the Secretary of State shall be competent evidence . . . of the treaties, international agreements other than treaties, and proclamations by the President of such treaties and international agreements other than treaties, as the case may be, therein contained, in all the courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States, and of the several States, without any further proof or authentication thereof."

AGREEMENT

BETWEEN

THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

THE UGANDA VIRUS RESEARCH INSTITUTE, MINISTRY OF HEALTH, REPUBLIC OF UGANDA

FOR

COOPERATION ON AN INTERNATIONAL CENTER OF EXCELLENCE IN RESEARCH IN RAKAI, UGANDA

The National Institute of Allergy and Infectious Diseases ("NIAID"), a component of the National Institutes of Health ("NIH"), an agency of the U.S. Department of Health and Human Services ("HHS"), and the Uganda Virus Research Institute ("UVRI"), a component of the Ministry of Health ("MOH"), of the Republic of Uganda, hereinafter referred to as the "Parties":

Recognizing the heavy burden of illness in Africa and other parts of the world resulting from infectious diseases;

Sharing a mutual interest in promoting research and training in infectious diseases on the basis of equal collaboration;

Acknowledging the Rakai Health Sciences Program (RHSP), a research program operated under the oversight of MOH/UVRI, has a long-standing history of conducting basic research and clinical research in the areas of HIV/AIDS and associated co-morbidities, and sexually transmitted diseases (STDs), aimed at improving treatment outcomes for these conditions; and

Desiring to build on the success of the International Centers for Excellence in Research (ICER) program initiated in Uganda in 2002;

Have agreed as follows:

Article 1. Scientific Focus

1. The Parties agree to continue ongoing activities, and to identify areas of mutual interest for expanded cooperation in scientific areas, including but not limited to, epidemiology,

medicine, molecular biology, virology, parasitology, immunology and microbiology with a focus on techniques for the prevention, diagnosis, and treatment of infectious diseases.

2. The focus of collaboration may include, but is not limited to the following:

- HIV/AIDS;
- STDs;
- Malaria;
- Other emerging and re-emerging pathogens;
- Other diseases of shared scientific interest.

Article 2. Mechanisms of Cooperation

The cooperation undertaken pursuant to this Agreement may include, but is not limited to:

- Collaborative research projects;
- Exchange of scientists and researchers;
- Scientific meetings, workshops and symposia;
- Training activities and consultations;
- Long-term assignment of scientists and researchers to undertake joint research;
- Enhancement and strengthening of biomedical/infectious disease research capacity, including clinical research infrastructure, data and information management systems, and sample repositories;
- Exchange of research materials, data, technology and scientific publications;
- Other forms of cooperation identified by mutual consent.

Article 3. Facilities and Management

1. The Parties' cooperation under this Agreement shall be undertaken primarily in Uganda at the Rakai Health Sciences Program laboratory in Kalisizo in the Rakai District of Uganda and field research sites associated with the ICER, or UVRI in Entebbe.

2. As its contribution to the development and support of the ICER, the MOH/UVRI shall provide:

- Access to RHSP and MOH/UVRI laboratory facilities for joint collaborative projects, particularly those facilities strengthened under the ICER program;

- Continued adherence to international biosafety standards for ICER laboratory facilities and equipment;

- Appropriately qualified research and support staff, as determined by the Parties, to perform collaborative projects and support functions;

- Laboratory and technical support for scientists on long-term assignments in ICER laboratories, as defined under the Exchange of Personnel section;

- Administrative support to facilitate research activities and to expedite all required clearances for U.S. and Ugandan scientists working under this program.

3. As its contribution to the development and support of the ICER, HHS/NIH/NIAID shall provide, subject to the availability of funds and personnel:

   - Scientific engagement with ICER-associated research facilities and laboratories;

   - Support to enhance laboratory capacity at the RHSP laboratory in Rakai, as determined through mutual discussion and research program needs;

   - Scientists for long-term research collaboration and joint scientific protocol implementation, as defined under the Exchange of Personnel section;

   - Assistance, with research tools and capabilities required for research projects;

   - Training and exchange opportunities in NIH laboratories.

4. Each Party shall designate in the future a project implementation coordinator(s) to plan, approve, and monitor activities under this Agreement. The coordinators, and/or their designees, shall communicate regularly and meet periodically, as necessary, to evaluate the activities carried out under this joint program, to resolve issues, and to ensure the efficient completion of collaborative research.

Article 4. Additional Participating Organizations

In addition to the Parties, other participants may join in cooperative activities under this Agreement. These participants may include individuals and institutions in the public, private, and academic sectors, State and local Governments of both countries; and other entities, as identified by the Parties. Additionally, the Parties may invite scientists, technical experts, and other entities of third countries, international organizations, and non-governmental organizations to participate, as appropriate, in projects and programs, with the mutual consent of the Parties or their implementing entities.

Article 5. Exchange of Personnel

Unless otherwise agreed in writing, the following provisions shall govern the assignment or exchange of personnel under this Agreement:

1. Whenever an exchange of personnel is contemplated, the Parties shall consult to ensure that the candidates are appropriately qualified to undertake the proposed activity, and to provide the required administrative and logistical support.

2. Exchange of personnel under individual projects shall be based on research requirements and approvals, provided during clearance of the project. No further clearances are envisaged for the exchange of such personnel.

3. When the long-term exchange of personnel is required outside the scope of individual projects, the Parties shall ensure that appropriate clearances are obtained from all responsible Ugandan and U.S. authorities. The Parties shall establish a formal agreement that documents the duration of the exchange, roles and responsibilities, and any other expectations regarding the performance and support of the personnel.

4. Subject to the availability of funds, designated ICER funding or funding provided by the Parties, shall be used to support salaries, insurance, transportation, housing, and all other expenses required to sustain the exchange of personnel.

5. All staff and contractors of each Party shall conform to the work rules and safety regulations that are in effect at the host facility.

Article 6. Exchange of Equipment

1. Unless otherwise agreed in writing, title to any equipment sent by one Party to the other shall remain with the sending Party. Any change in the title to the equipment shall be decided by mutual agreement in writing.

2. The Parties shall mutually determine the use of such equipment.

Article 7. Laws and Regulations

Each Party shall conduct the cooperative activities pursuant to this Agreement in accordance with relevant applicable laws, regulations, procedures, policies, guidelines and subject to the availability of appropriated and other funds and personnel.

Article 8. Protection of Human and Animal Subjects in Research

Both Parties acknowledge the importance of the protection of human and animal subjects in any research, public-health or medical program. In recognition of this, both Parties agree to follow the laws and regulations for the protection of human and animal subjects adopted by the United States of America and the Republic of Uganda.

Article 9. Intellectual Property and Business-Confidential Information

The Parties recognize the work carried out under this Agreement could produce patentable results and other intellectual property. The provisions set forth in Annex I of this Agreement shall guide the allocation of rights to intellectual property and the treatment of business-confidential information created or furnished in the course of cooperative activities under this Agreement, except as otherwise specifically decided by the Parties or their designees pursuant to Section IIA of this Annex.

Article 10. Publication of Scientific Findings

Consistent with the relevant policies, laws and regulations of the Parties, scientists affiliated with either Party should publish their findings, both jointly and as individuals, with authorship decided according to internationally accepted conventions for scientific publications. In any publication specifically related to work undertaken in areas covered by this Agreement, the Parties should make an appropriate reference to the ICER program. The Parties should make scientific and technological information derived from collaborative activities under this program available to the scientific community, in accordance with the normal procedures of the Parties, and to the extent consistent with the implementing arrangements. Scientists affiliated with either Party should conduct their research in a fully transparent manner with their collaborating partners, and readily disclose any and all related collaborations that might pose a conflict with research supported under this collaboration.

Article 11. General Provisions

1. The U.S. Government and the Government of the Republic of Uganda may provide funding support for activities under this Agreement depending on the availability of resources. The Parties may seek additional funding and active participation from governmental, non-governmental, private-sector, foundation, and other sources, as necessary and consistent with usual and customary practice, to support individual projects. The Parties may expend funds based on each Party's approved budgets for jointly approved, collaborative research projects and related activities.

2. Both Parties recognize work under this Agreement can involve numerous exchanges of administrative and scientific personnel throughout each year. Both Parties agree to facilitate

scientific collaboration by using best efforts to ensure the rapid completion of necessary clearances (exit permission by the sending country and visa issuance by the receiving country) on a priority basis, subject to each Party's respective laws and regulations.

3. Each Party shall facilitate and encourage, as appropriate, and in accordance with its laws and regulations, the exchange of research materials including specimens, data, and equipment necessary to undertake the collaborative activities conducted under this Agreement.

4. Materials and equipment introduced into Uganda by HHS/NIH/NIAID, its contractors or grantees for the purpose of undertaking activities under this Agreement shall be exempt from customs duties, local taxes, or value-added tax (VAT) imposed by the Republic of Uganda.

5. Each Party agrees that all materials provided by the other Party shall not be distributed to another organization or individual without the written authorization of the providing Party, except as required by law. Any transfer of biological materials under this Agreement shall be executed in full accordance with applicable law and each Party's rules, regulations, policies, and safety precautions.

Article 12. Periodic Review Process

The activities of the ICER program shall be reviewed at annual conference calls or joint meetings attended by representatives of the Parties and collaborating organizations, as necessary. Reports based on these meetings shall be submitted to MOH/UVRI and HHS/NIH/NIAID. Areas for periodic review may include:

- Scientific progress;
- Research capacity-strengthening activities;
- Annual budgets;
- Exchange of personnel.

Article 13. Duration, Amendment and Termination

1. This Agreement shall enter into force upon signature and shall remain in force for five years, unless terminated by either Party upon ninety (90) days written notice to the other Party. It may be amended, extended, or terminated by mutual written agreement of the Parties.

2. The termination of this Agreement shall not affect the validity or duration of any arrangements entered into pursuant to the Agreement prior to its termination.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective governments, have signed this Agreement.

Done at Ministry of Health, in duplicate, on 9/05/2017, in the English language.

FOR MINISTRY OF HEALTH, UGANDA

SIGNATURE :

NAME : Diana Atwine

DESIGNATION : Permanent Secretary

WITNESS
UGANDA VIRUS RESEARCH INSTITUTE, ENTEBBE

SIGNATURE :

NAME : Prof. Anthony Mbonye

DESIGNATION : Acting Director General Health Services

Done at Kampala, Uganda, in duplicate, on 9 May 2017, in the English language.

FOR THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SIGNATURE :

NAME : DEBORAH R. MALAC

DESIGNATION : Ambassador of the United States to the Republic of Uganda

WITNESS
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SIGNATURE : [signature]

NAME : Steven Reynolds

DESIGNATION : Senior Clinician NIAID/NIH

09/05/2017

ANNEX I

Intellectual Property Rights

I. General Obligation

The Parties shall ensure adequate and effective protection of intellectual property created or furnished under this Agreement and relevant implementing arrangements. Rights to such intellectual property shall be allocated as provided in this Annex.

II. 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 mean the subject matter listed in Article 2 of the Convention Establishing the World Intellectual Property Organization, done at Stockholm, July 14, 1967 and may include other subject matter as agreed by the Parties.

C. Each Party shall ensure, through contracts or other legal means with its own participants, if necessary, that the other Party can obtain the rights to intellectual property allocated in accordance with this Annex. This Annex does not otherwise alter or prejudice the allocation between a Party and its participants, which shall be determined by that Party's laws and practices.

D. Except as otherwise provided in this Agreement, disputes concerning intellectual property arising under this Agreement shall 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 of 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 obligations under this Annex.

III. Allocation of Rights

A. Each Party shall be entitled to a worldwide, non-exclusive, irrevocable, royalty-free license to translate, reproduce, and publicly distribute monographs, 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 Agreement 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 paragraph IIIA above, shall be allocated as follows:

(1) Prior to participation in cooperative activities under this Agreement by a visiting researcher, the host Party or its designee and the Party or its designee employing or sponsoring the visiting researcher may discuss and determine the allocation of rights to any intellectual property created by the visiting researcher. Absent such a determination, visiting researchers shall receive rights, awards, bonuses, and royalties in accordance with the policies of the host institution. For purposes of this Agreement, a visiting researcher is a researcher visiting an institution of the other Party (host institution) and engaged in work planned solely by the host institution.

(2)(a) Any intellectual property created by persons employed or sponsored by one Party under cooperative activities other than those covered by Paragraph III.(B)(1) shall be owned by that Party. Intellectual property created by persons employed or sponsored by both Parties shall be jointly owned by the Parties. In addition, each creator shall be entitled to awards, bonuses and royalties in accordance with the policies of the institution employing or sponsoring that creator.

(b) Unless otherwise agreed in an implementing or other arrangement, each Party shall have within its territory a right to exploit or allow others to exploit intellectual property created in the course of the cooperative activities.

(c) The rights of a Party outside its territory shall be determined by mutual agreement considering the relative contributions of the Parties and their participants to the cooperative activities, the degree of commitment in obtaining legal protection and licensing of the intellectual property and such other factors deemed appropriate.

(d) Notwithstanding paragraphs III.B(2)(a) and (b) above, if either Party believes that a particular project is likely to lead to or has led to the creation of intellectual property not protected by the laws of the other Party, the Parties shall immediately hold discussions to determine the allocation of rights to the intellectual property. If an agreement cannot be reached within three months of the date of the initiation of the discussions, cooperation on the project in question shall be terminated at the request of either Party. Creators of intellectual property shall nonetheless be entitled to awards, bonuses and royalties as provided in paragraph III.B(2)(a).

(e) For each invention made under any cooperative activity, the Party employing or sponsoring the inventor(s) shall disclose the invention promptly to the other Party together with any documentation and information necessary to enable the other Party to

establish any rights to which it may be entitled. Either Party may ask the other Party in writing to delay publication or public disclosure of such documentation or information for the purpose of protecting its rights in the invention. Unless otherwise agreed in writing, the delay shall not exceed a period of six months from the date of disclosure by the inventing Party to the other Party.

IV. Business-Confidential Information

In the event that information identified in a timely fashion as business-confidential is furnished or created under this 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, and 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.