JOINT STATEMENT BETWEEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

AND

THE MINISTRY OF HEALTH AND FAMILY WELFARE OF THE REPUBLIC OF INDIA

ON

COLLABORATION ON PREVENTION OF SEXUALLY TRANSMITTED DISEASES AND HIV/AIDS

On October 17, 2005, the Government of the United States of America ("United States" or "U.S.") and the Government of the Republic of India ("India") signed an Agreement on Science and Technology (S&T Agreement) to encourage cooperation to promote advances in science and technology.

On June 13, 2000, and again on June 26, 2006, the Union Minister of Health and Family Welfare of India and the Secretary of the Department of Health and Human Services of the United States signed a Joint Statement on Prevention of Sexually Transmitted Diseases (STDs) and Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV/AIDS), each Joint Statement to cover a five-year period. Under the provisions of these Joint Statements, U.S. and Indian scientists have undertaken a wide range of successful and collaborative prevention research efforts, including studies of behavioral change strategies, epidemiological and operational research, and intervention strategies for the prevention of HIV/AIDS and co-morbidities among injecting-drug abusers and other high-risk groups. The scientific productivity of these efforts has affirmed the value of this cooperation.

Recognizing the pandemic of STDs and HIV/AIDS and its effect in the world, the Department of Health and Human Services of the United States and the Ministry of Health and Family Welfare of India (hereinafter the "Participants") intend to continue and renew cooperation in the field of STDs and HIV/AIDS prevention research, as outlined below:

Part One

The Participants intend to promote and develop cooperation in the fields of STDs and HIV/AIDS basic, clinical, and translational prevention research, training, and research infrastructure strengthening on the basis of reciprocity and mutual benefit. The following are to be the principal implementing governmental departments and agencies:

Government of India Implementing Ministries and Agencies:

- 1. The Indian Council of Medical Research (lead agency), Department of Health Research; and
- 2. The National AIDS Control Organization of the Ministry of Health and Family Welfare; and
- 3. The Department of Biotechnology of the Ministry of Science and Technology

U.S. Government Implementing Departments and Agencies:

- 1. The National Institutes of Health (lead agency); and
- 2. The Centers for Disease Control and Prevention of the Department of Health and Human Services

In addition to the entities identified above, there may be other organizations and institutions engaged in the activities, with the approval of both Participants. These additional entities may come from the public, private, and academic sectors, State and local Governments in both countries, and other entities, as identified and mutually approved.

Part Two

The main areas of cooperation may include, but may not be limited to, the following:

- Developing and evaluating innovative, sustainable intervention strategies for the prevention and/or treatment of HIV/AIDS and its associated co-morbidities and STDs;
- Supporting Indian Ministry of Health and Family Welfare efforts in the development, evaluation, and expansion of interventions to reduce the burden of tuberculosis, malaria, cancer, and other related co-morbidities in vulnerable populations;
- c. Researching HIV/AIDS vaccines, microbicides, diagnostic kits, and/or new therapeutics, and studies to evaluate the impact of prevention or therapeutic interventions;
- d. Supporting research on the development of new treatment methodologies, including point of care technologies, assays for incidence estimates, and studies to understand the impact of social, cultural, and environmental factors on the dynamics of HIV/AIDS;
- e. Developing culturally sensitive and appropriate, confidential approaches to voluntary counseling and testing, especially for high-risk groups and other vulnerable groups in the general population;
- f. Developing effective methods and strategies for collecting reliable and valid HIV and STD surveillance data for joint research projects, quality control of data and data analysis, the use of data for effective decision-making, and systematic monitoring and evaluation;
- g. Developing new strategies for enhancing blood safety and reducing HIV transmission in health-care settings;
- h. Strengthening research capacity among health-care professionals and others involved in the care and treatment of People Living with AIDS (PLWA) to conduct studies on STDs and HIV/AIDS;
- i. Developing programs to strengthen and sustain research capacity and infrastructure in the areas

- of prevention, access to care, and treatment for HIV at the National and State levels;
- j. Developing and evaluating new programmatic strategies to encourage effective antenatal screening and prevention of mother-to-child transmission of HIV;
- k. Supporting research on prevention programs that focus on maternal and child health, in the context of HIV infection; and
- Developing and assessing integrated strategies for the prevention, management and treatment of HIV-associated complications, including cancer, hepatic, and other co-morbidities.

Part Three

Modes of cooperation between the Participants may include, but may not be limited to, the following:

- Continuing the Joint Working Group (JWG) mechanism established under prior Joint Statements;
- Increasing collaboration among scientists in both countries to conduct research through projects under a call-for-proposals mechanism, and research training related to STDs and HIV/AIDS, including basic, clinical, and operational/translational studies;
- c. Exchanging information and scientific findings, and the sharing of experiences;
- d. Attending professional, scientific, and training meetings by specialists from both countries;
- e. Establishing new and reinforcing existing direct links between appropriate institutions of both countries, including the identification and encouragement of U.S.-India partner institute arrangements;
- f. Continuing to support a state-of-the-art, non-human-primate breeding facility in India for conducting research on microbicides, vaccines, and therapeutics; and
- g. Continuing to support Centers of Excellence in research, training, and public health, which should foster collaboration in basic, applied, and epidemiologic investigations.

Part Four

The JWG is intended to develop strategic plans for collaboration and to facilitate the expedited review and clearance of meritorious proposals and other activities. It should meet at least once each year, and should designate an Executive Secretariat in each country that maintains regular communication and undertakes joint activities throughout the year. The JWG should include Indian and U.S. members, identified and mutually decided upon by the Participants. Each Participant may designate up to two JWG Co-Chairs, and may communicate the names of the Co-chairs in advance of each meeting. The JWG should:

 Review program plans and recommend new areas of cooperation, utilizing recommendations derived from its members and technical experts, technical workshops, scientific conferences, and collaborating scientists;

- b. Recommend measures to the Participants to ensure the program operates effectively, efficiently, and within mutually accepted timelines;
- c. Address issues that require joint resolution and which the Participants cannot address effectively outside of the JWG; and
- d. Prepare summary reports, as needed, on activities conducted under this Joint Statement to highlight key achievements, and assist in prioritizing future areas for enhanced scientific cooperation.

Part Five

The Participants intend to engage in all activities pursuant to this Joint Statement in accordance with the laws and regulations of the United States and India. Such activities are to be subject to the availability of personnel, resources, and funds, including supporting the program expenses related to funding of projects, exchange visits of scientists under approved projects, and expenses related to convening JWG meetings. The Participants intend to continue to develop steps for implementing activities envisioned in this Joint Statement through administrative and scientific consultations after the signing of this Joint Statement.

Part Six

The Participants acknowledge the importance of protections for human and animal subjects in any research, public-health activity, or medical program. In recognition of this importance, both India and the United States note that each Participant has adopted laws, regulations, and policies on the protection of human and animal subjects, and each Participant intends to engage in all activities in accordance with the applicable laws, regulations and policies of the United States and India.

Part Seven

The Participants recognize the work carried out under this Joint Statement may produce patentable results and lead to the publication of scientific findings. The allocation of such intellectual property rights to patents may be determined by mutual agreement of the Participants, if they so desire, and on a case by case basis.

The Participants encourage investigators funded under the joint activities described herein to publish their findings, both jointly and individually. In any publication specifically related to work funded or approved under this Joint Statement, investigators should make an appropriate reference to the Joint Statement and the collaborative effort it establishes.

Part Eight'

The Participants recognize work under this Joint Statement may involve numerous exchanges of administrative and scientific personnel throughout each year. The Participants should seek the necessary clearances (exit permission by the sending country and visa issuance by the receiving country) on a priority basis, subject to their respective laws and regulations.

Part Nine

This Joint Statement becomes operative on the date of signature, and should remain operative for five years. Either Participant should endeavor to provide three months' advance written notice of its intent to discontinue this Joint Statement. The Joint Statement is not intended to create binding, legal obligations between the Participants.

Signed at Bethesda, Maryland, USA, on 10/20/11, with two originals in the English language.

Signed at New Delhi, India, on Oct 25, 20, with two originals in the English language.

For the Department of Health and Human Services of the United States of America

For the Ministry of Health and Family Welfare of the Republic of India

Dr. Francis S. Collins

Director,

National Institutes of Health

Mode - or the

Dr. V.M. Katoch

Secretary,

Department of Health Research