

**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 DIABETES RESEARCH**

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 Cooperation (S&T Agreement) to encourage cooperation to promote advances in science and technology.

Diabetes is a debilitating disease that affects tens of millions of people in the U.S. and India, and it is amongst the leading causes of death worldwide. Diabetes lowers average life expectancy, increases cardiovascular disease, and is a leading cause of kidney failure, lower limb amputations, and adult onset blindness. In addition to the substantial human health costs, the estimated total financial cost for diabetes in both countries is staggering, and projected to increase substantially in coming years.

Recognizing the potential benefits of collaborative scientific approaches in an area marked by complex technologies and related disciplines, and recognizing the important benefits in reduction and prevention of diabetes and related risk factors, the Indian Council of Medical Research, Department of Health Research of the Ministry of Health and Family Welfare, India; the Department of Biotechnology of the Ministry of Science and Technology, India; and the National Institutes of Health of the Department of Health and Human Services, United States, (hereinafter the “Participants”), intend to establish a joint collaborative research program in diabetes.

The main purpose of this Joint Statement is to initiate a health research relationship between the Participants to generate a better understanding of the molecular and biological mechanisms underlying diabetes, to characterize the genetic, social and environmental determinants, and to identify innovative approaches for improving prevention and treatment of diabetes. Joint efforts may also focus on developing cost-effective tools and approaches to translate research results into policies and actions to improve the public health.

**Part One**

The Participants intend to promote and develop cooperation in the field of basic, clinical, and translational research in the areas of diabetes mellitus, on the basis of reciprocity and mutual benefit. The following are to be the principal implementing governmental departments and agencies:

### **U.S. Government Implementing Departments and Agencies:**

1. The National Institutes of Health of the Department of Health and Human Services

### **Government of India Implementing Ministries and Agencies:**

1. The Indian Council of Medical Research of the Ministry of Health and Family Welfare; and
2. The Department of Biotechnology of the Ministry of Science and Technology

Participants may mutually decide to invite other organizations and institutions to engage in the cooperative research activities described in this Joint Statement. These additional entities may come from the public, private, and academic sectors, or from state and local governments in the countries of the Participants.

### **Part Two**

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

- a. Identifying genetic and environmental etiologic factors and pathogenic mechanisms underlying development of diabetes and its complications;
- b. Developing improved approaches and diagnostic tools to identify those with and at risk of diabetes and its complications;
- c. Developing and evaluating innovative, sustainable intervention strategies for the prevention and/or treatment of diabetes and its associated co-morbidities;
- d. Developing and testing new treatment methodologies, including point of care and telemedicine technologies, diabetes self-management approaches, and improved technologies for insulin delivery and monitoring of glycemic control;
- e. Studying the impact of social, economic, cultural and environmental factors on diabetes risk and management;
- f. Developing, comparing and analyzing diabetes data sets and registries;
- g. Developing effective methods and strategies for collecting reliable and valid diabetes 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;
- h. Identifying and overcoming barriers to translating clinical trial results into improved prevention and management of diabetes;
- i. Comparing different models of delivery of diabetes prevention and care and assessing cost-effectiveness;
- j. Developing and assessing integrated strategies for the prevention, management and treatment of diabetes mellitus.

### **Part Three**

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

- a. Increased collaboration among investigators in both countries to conduct collaborative research projects in mutually identified areas through funding opportunities such as Requests for Applications, Requests for Proposals, or Program Announcements;
- b. Exchange of investigators under collaborative research projects, training, and scientific workshops;
- c. Exchange of scientific information through publications, lectures, workshops, seminars and the co-sponsorship of such endeavors;
- d. Establishment of a Joint Steering Committee (JSC) that communicates regularly to identify new areas of cooperation, evaluate progress, and ensure the joint program operates smoothly.

### **Part Four**

The JSC is intended to develop strategic plans for collaboration, recommend areas and topics for joint workshops, develop collaborative research project solicitations, facilitate the expedited review and clearance of collaborative proposals, and foster other joint activities to advance research on diabetes mellitus. The Indian and U.S. members of the JSC may be identified by the Participants, and a co-chair may be chosen by each side. The JSC may meet regularly via videoconference, teleconference, web-assisted conference, or in face-to-face meetings when both Participants deem necessary. It is intended that expenses such as travel, accommodation, insurance, and local transport of the JSC members would be borne by the sending Participant, whereas organizational expenses of the JSC meeting would be borne by the host Participant. It is intended that organizational expenses of joint workshops would be borne by the host Participant and travel expenses would be borne by the sending Participant; expenses for joint workshops may also be borne by other organizations and institutions, with the written concurrence of both Participants.

### **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 investigators under approved projects, and expenses related to convening meetings. The Joint Statement does not create binding legal obligations between the Participants. It is understood that if there is to be an exchange or transfer of biological materials under this Joint Statement, Participants may require prior approvals. The Participants intend 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. It is intended that all activities be undertaken 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. It is intended that worldwide rights to any invention created solely by a Participant are to be solely owned by that Participant and those created jointly by more than one Participant are to be jointly-owned by the Participants. The allocation of intellectual property rights 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. 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 exchanges of administrative and scientific personnel, and the exchange of biological materials. The Participants should seek any needed clearances (for example, exit permission by the sending country and visa issuance by the receiving country, as applicable) on a priority basis, subject to their respective laws and regulations.

**Part Nine**

This Joint Statement becomes operative on the date of signature, and is intended to remain operative for five years. Either Participant should endeavor to provide three months' advance written notice of its intent to discontinue this Joint Statement.

Signed at Washington, DC this 12th day of June in two originals, each in English and Hindi languages, in duplicate.

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



Kathleen Sebelius

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

