IMPLEMENTING ARRANGEMENT
BETWEEN
THE INDIAN COUNCIL OF MEDICAL RESEARCH,
DEPARTMENT OF HEALTH RESEARCH,
MINISTRY OF HEALTH AND FAMILY WELFARE OF THE REPUBLIC OF INDIA
AND
THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES,
NATIONAL INSTITUTES OF HEALTH,
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA
ON
COLLABORATION ON DIABETES RESEARCH

The Indian Council of Medical Research ("ICMR") of the Department of Health Research ("DHR") of the Ministry of Health and Family Welfare ("MOHFW") of the Republic of India and the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), part of the National Institutes of Health ("NIH"), an agency of the U.S. Department of Health and Human Services ("HHS") of the United States of America, and, hereinafter collectively referred to as the "Participants" and individually as "Participant,"

Recognizing that the Government of the United States of America and the Government of the Republic of India concluded an Agreement on Science and Technology Cooperation, signed at New Delhi on September 20 and 23, 2019, respectively (hereinafter referred to as the "S&T Agreement");

In accordance with the Memorandum of Understanding between the HHS and the MOHFW concerning Cooperation in the field of Health and Biomedical Sciences, signed at New Delhi on September 28, 2021;

Recognizing that HHS and MOHFW signed a Joint Statement for the Collaboration on Diabetes Research on June 12, 2012, which was extended through an exchange of letters dated May 10 and 30, 2017, under which the Participants are named as implementing agencies and established a joint collaborative research program in diabetes ("Joint Program");

Seeking to build upon the success of the Joint Program;

Intend the following:

Section 1. Scientific Focus

1. The Participants intend to sustain and promote cooperation in the field of basic, clinical, and translational research in the areas of diabetes mellitus, on the basis of reciprocity and mutual benefit.

2. The Participants intend to continue ongoing activities, and to identify areas of mutual interest for expanded cooperation in scientific areas 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.

3. The focus of Participants' collaboration may include, but is not necessarily limited to, the following:

   a. Identifying genetic and environmental etiologic factors and pathogenic mechanisms underlying development of diabetes and its complications;
   b. Studying the interaction of diabetes and co-morbid infectious diseases;
   c. Developing improved approaches and diagnostic tools to identify those with and at risk of diabetes and its complications;
   d. Developing and evaluating innovative, sustainable intervention strategies for the prevention and/or treatment of diabetes and its associated co-morbidities;
   e. 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;
   f. Studying the impact of social, economic, cultural, and environmental factors on diabetes risk and management;
   g. Developing, comparing and analyzing diabetes data sets and registries;
   h. 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;
   i. Identifying and overcoming barriers to translating clinical trial results into improved prevention and management of diabetes;
   j. Comparing different models of delivery of diabetes prevention and care and assessing cost-effectiveness;
   k. Developing and assessing integrated strategies for the prevention, management, and treatment of diabetes mellitus; and
   l. Any other areas of cooperation identified mutually.

Section 2. Mechanisms of Cooperation

The cooperation carried out pursuant to this Implementing Arrangement ("IA") may include, but is not limited to:

- Collaborative research projects;
- Exchange of scientists and researchers;
- Scientific meetings, workshops and symposia;
- Training activities and consultations;
- Other forms of cooperation as mutually identified.

Section 3. Implementation and Administration

The Participants intend to establish a Joint Working Group (JWG) constituting members from both countries to develop strategic plans for collaboration, identify areas and topics for joint workshops, develop bilateral solicitations with the intent of establishing collaborative research projects, facilitate

the expedited review and clearance of collaborative research proposals, and foster other joint activities to advance research on diabetes mellitus. The Participants intend to identify the Indian and U.S. members of the JWG and each Participant intends to select a co-chair. The Participants intend for the JWG to meet regularly via videoconference, teleconference, web-assisted conference, or in face-to-face meetings whenever both Participants deem necessary. The sending Participant expects to bear expenses such as travel, accommodation, insurance, and local transport of the JWG members, whereas organizational expenses of the JWG meeting are expected to be borne by the host Participant. Similarly, the Participants expect organizational expenses of joint workshops to be borne by the host Participant and travel expenses to be borne by the sending Participant; expenses for joint workshops may also be borne by other organizations and institutions, with the written concurrence of Participant.

Each Participant is expected to designate a JWG member for secretariat functions, to plan and monitor activities under this IA. These executive secretaries, and/or their designees, are expected to communicate regularly and meet periodically, as necessary, to evaluate the cooperative activities carried out under this IA, to resolve issues, and to ensure the efficient completion of collaborative research.

Section 4. Additional Participating Organizations

In addition to the Participants, other entities and individual scientists may join in cooperative activities under this IA as mutually decided by the Participants. These other entities may include individuals and institutions in the public, private, and academic sectors, including other ICMR and/or NIH institutes, state and local Governments, and other entities of both countries, as identified by Participants. Additionally, the Participants may mutually decide to invite scientists, technical experts, and other entities of third countries, international organizations, and non-governmental organizations to participate, as appropriate, in activities under this IA, with the mutual consent of the Participants.

Section 5. Exchange of Personnel

The Participants recognize work under this IA may involve exchanges of administrative and scientific personnel. The Participants intend to 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.

Section 6. Laws and Regulations

All activities pursuant to this IA are expected to be conducted in accordance with applicable laws, regulations, procedures, policies and guidelines prevailing in the countries of respective Participants and subject to the availability of personnel, resources and appropriated funds.

Section 7. Protection of Human and Animal Subjects and Transfer of Biological Materials

Both Participants acknowledge the importance of the protection of human and animal subjects in any research, public-health, or medical program. In recognition of this, both Participants intend that activities under this IA are to be carried out in accordance with the applicable laws, regulations, and policies for the protection of human and animal subjects, and for the transfer of data and/or

biological material, adopted by the Republic of India and the United States of America. If there is any exchange or transfer of biological materials under this IA, the Participants may require prior approvals in accordance with their respective applicable laws, regulations, policies, and safety precautions.

Section 8. Intellectual Property and Publications

1. The Participants recognize that the work carried out under this IA could produce patentable results, and lead to the publication of scientific findings. The Participants intend that the treatment of any intellectual property created or furnished under this IA, as well as the allocation of rights to any such intellectual property, is governed by Annex I of the S&T Agreement. Provisions for the protection of classified information and unclassified export-controlled information and equipment are governed by Annex II of the S&T Agreement.

2. The Participants intend to encourage scientists of both countries collaborating under the Joint Program to publish their findings, both jointly and as individuals. In any publication specifically related to work carried out in areas covered by this IA, the Participants intend to make an appropriate reference to the IA. The Participants intend to make scientific and technological information derived from collaborative activities under this IA available to the scientific community, in accordance with the normal procedures of the participating entities. Investigators are expected to endeavor to conduct their research in a fully transparent manner with their collaborating partners, and disclose all related collaborations that might pose a conflict with research supported under this IA.

Section 9. General Provisions

1. The Government of the United States of America and the Government of the Republic of India may provide funding support for activities under this IA, depending on the availability of resources. The Participants 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 Participants may expend funds based on the individual, approved budgets of jointly approved, collaborative research projects and related activities.

2. This IA and any activities hereunder are subject to, and governed by, the S&T Agreement.

3. It is acknowledged that each Participant may possess non-public information that is proprietary to it or to third parties collaborating with it. Any such information is expected only to be shared between the Participants under a separate confidentiality disclosure arrangement specifically covering such information. As noted, provisions for the protection of classified information and unclassified export-controlled information are governed by Annex II of the S&T Agreement. Except as required by applicable law, the receiving Participant does not intend to use the non-public information for purposes other than those specified without the prior written consent of the transmitting Participant.

4. The IA is not an international agreement and does not create legal binding obligations between the Participants.

Section 10. Periodic Review Process

The activities conducted pursuant to this IA are expected to be reviewed at annual conference calls or joint meetings, attended by representatives of the Participants and the collaborating organizations, as necessary. Reports based on these meetings should be submitted to MOHFW/DHR/ICMR and HHS/NIH/NIDDK. Areas for periodic review may include:

- Scientific progress
- Capacity building activities
- Exchange of personnel

Section 11. Resolution of Issues

Any question or issue/difficulty arising in the application, interpretation, or implementation of the provisions of this IA may be amicably resolved between the Participants through good faith negotiation and consultation.

Section 12. Commencement, Duration, Modification and Discontinuation

1. This IA may commence upon signature of the Participants and is intended to continue for ten years. This IA may be modified or extended by mutual written decision of the Participants.
2. Either Participant may discontinue its cooperation under this IA and should endeavor to provide at least ninety (90) days advance notice in writing to the other Participant. The discontinuation of this IA is not intended to affect the validity or duration of any arrangements entered into pursuant to the IA prior to its discontinuation.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Institutions, have signed this Implementation Arrangement.

Signed in two originals in the English language.

FOR THE INDIAN COUNCIL OF MEDICAL RESEARCH, DEPARTMENT OF HEALTH RESEARCH, MINISTRY OF HEALTH AND FAMILY WELFARE OF REPUBLIC OF INDIA

Rajiv Bahl

Place: New Delhi, India

Date: 15 June 2023

FOR THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

Griffin Rodgers

Place: Bethesda, MD, USA

Date: 29 June 2023.