MEMORANDUM OF UNDERSTANDING

among

The Department of Biotechnology, Govt. of the Republic of India (DBT)and
The Indian Council of Medical Research (ICMR)
and
International AIDS Vaccine Initiative (IAVI)

This Tripartite Memorandum of Understanding ("**MOU**") is entered by:

The Department of Biotechnology ("DBT"), a Department of the Ministry of Science & Technology, Government of the Republic of India, with an address of Block-2,3 CGO Complex, Lodhi Road, New Delhi-110003, India;and

AND

Indian Council of Medical Research ("ICMR"), the apex body in India for the formulation, coordination and promotion of biomedical research, funded by the Government of the Republic of India, with an address of V. Ramalingaswami Bhawan, P. B. 4911, Ansari Nagar, New Delhi-110029, India;

AND

International AIDS Vaccine Initiative Inc. ("IAVI"), a not-for-profit corporation organized under the laws of the state of Delaware, USA, with its principal office at 125 Broad Street, 9th Floor, New York, NY10004, USA.

DBT: DBT's vision is to attain new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice – specially for the welfare of the poor. It serves the areas of research and development, infrastructure creation, generation of human resources, popularization of biotechnology, promotion of industries in the field of biotechnology, creation of centres of excellence, implementation of biosafety guidelines for genetically modified organisms and recombinant DNA products and biotechnology-based programs for societal benefits.

ICMR: ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research. It is one of the oldest medical research bodies in the world. It is an autonomous body under the Department of Health Research, Ministry of Health and Family Welfare (MOHFW), Government of the Republic of India.

IAVI: IAVI's mission is to translate scientific discoveries into affordable, accessible public health solutions for the people who need them most. IAVI is pioneering an access-first approach to biomedical innovation, developing vaccines and antibodies in and for the developing world and seeking to accelerate their introduction in low-income countries.

Herein after referred to individually as a "Party" and collectively as the "Parties".

WHEREAS

ICMR and DBT each of entered a separate Memorandum of Understanding with IAVI.

DBT and IAVI entered into a Memorandum of Understanding (MoU)on July 7, 2005 for a five-year period; they extended that memorandum on the same terms and conditions, for an additional period of fiveyears ending on 7th July 2015; and extended again for an additional five years ending 7th July 2020.

ICMR and NACO, MoH&FW and IAVI signed an agreement in 2000. Parties entered into Vaccine Development and Evaluation Agreement under this MoU in May, 2001, extended through Addendum to April, 2007 and further extended to April, 2012. Further ICMR and IAVI entered into Memorandum of Understanding dated as of 10th November, 2014 for a five-year period.

Under their respective last fully executed bilateral memoranda, the Parties agreed to collaborate and contribute their experiences and resources on AIDS vaccine development and evaluation of one or more safe and effective AIDS vaccines primarily for use in, but not limited to, India.

WHEREAS, under their memorandum of understanding, DBT and IAVI successfully established the following research projects and initiative:

- HIV Vaccine Translational Research Laboratory:
  THSTI (an autonomous institute of the DBT) and IAVI in 2009, cofounded, and co-funded the HIV Vaccine Program ("HIV Vaccine Translational Research Laboratory – HVTR"), with a focus on designing, testing and implementing high-throughput (HT) strategies for HIV-1 envelope-based immunogen screening and prioritization. In 2019, the two expanded the scope of their collaboration beyond HIV Vaccine Program, to establish and co-operate in a new research program entitled the Antibody Translational Research Program that is focused at setting up technologies, assays, protocols, and relevant skill-sets in the areas of antibody discovery, antibody characterization such as epitope mapping and develop ability assays, and preclinical evaluation in suitable animal models, etc.

- Indo-South Africa Bilateral Collaboration on HIV/TB:
  The Department of Biotechnology, the Department of Science and Technology, Government of India and the Department of Science and Technology, Government of South Africa and the South African Medical Research Council embarked on the program with the aim to facilitate partnerships between research institutions in India and South Africa. This programme is implemented under India South Africa S&T Cooperation by DBT and DST jointly with DST (DSI) South Africa and IAVI is an agency for programme monitoring identified by DST. This collaboration synergistically advances discovery efforts towards development of new technologies and products for prevention and management of HIV/AIDS and TB by building scientific leadership capacity, fostering a sustainable environment for translational research and enhancing clinical capability/capacity.

- India-Netherland Bilateral Collaboration:
  The Department of Biotechnology, Government of India in collaboration with the Erasmus University Medical Centre (Netherlands) is implementing a project focusing on population-based research studies to understand disease dynamics towards effective management of prevention and treatment of HIV/AIDS, including co- morbidities and co-infections. The Department of Biotechnology has identified IAVI as an agency for programme monitoring unit for this collaborative program. This partnership enables comparative study of unique features of Indian and European epidemic across populations with different genetic and immunological backgrounds as well as different HIV strain and subtypes (Subtype C in India and Subtype B in Europe) towards identification and validation of unique/ common biomarkers associated with disease pathogenesis and control.

- DBT-ICMR-IAVI National Clinical Research Program (CoHRPICA) on HIV:

  The Department of Biotechnology (DBT), and Indian Council of Medical Research (ICMR), Government of India in collaboration with International AIDS Vaccine Initiative (IAVI) are implementing a National HIV Cohort Program. The Cohorts for HIV Resistance and Progression in Indian Children and Adults (CoHRPICA) program, launched in 2017, represents the first nationwide, multi-site, systematic and structured effort aimed at studying HIV in Indian populations of interest. As a longitudinal, open cohort study, it will also establish a centralized National Biorepository to provide access to a diverse set of well- characterized samples, and an integrated National Database to provide controlled access to behavioral, clinical and molecular data associated with the samples.

WHEREAS, under their memorandum of understanding, ICMR and IAVI successfully established thefollowing research projects and initiative:

- Phase-I Clinical trials for HIV vaccine candidates:
  Three Phase-I HIV vaccine clinical trials in India helped build significant capacities in participatory research, bioethics, advocacy, socio-behavioral change communication and training for vaccine development in the country. The trials were conducted in Pune and Chennai at ICMR's premier research institutes - National AIDS Research Institute (NARI) and National Institute for Research on Tuberculosis (NIRT) respectively.

- NARI-AIDS Rural Research Initiative in Maharashtra (NARRIM):
  NARRIM was established with a focus on creating community-based open cohorts to understand the dynamics of the HIV epidemic in rural settings. This initiative represented a marked shift in achieving population-level synergies to both inform product development and enable global access for future products.

- DBT-ICMR-IAVI National Clinical Research Program (CoHRPICA) on HIV:
  The Cohorts for HIV Resistance and Progression in Indian Children and Adults (CoHRPICA) program, launched in 2017, represents the first nationwide, multi-site, systematic and structured effort aimed at studying HIV in Indian populations of interest. As a longitudinal, open cohort study, it will also establish a centralized National Biorepository to provide access to a diverse set of well-characterized samples, and an integrated National Database to provide controlled access to behavioral, clinical and molecular data associated with the samples.

- ICMR-MEA led India-Africa Health Sciences Collaboration:
  The India-Africa Health Sciences Collaborative Platform (set up as an outcome of the India-Africa Health Sciences Meet, September 2016), aims to invigorate health R&D ecosystems in the two regions through innovative joint research and capacity building efforts to help boost product development, medical education, technology transfer, and trade and commerce. Pillared on the mandate of the Hon'ble Prime Minister of India announced at the India Africa Forum Summit III, it capitalizes on regional diversities and complementary strengths to collaboratively pursue shared health goals.

WHEREAS, it is recognized that there are significant and ever-expanding global health challenges posed by various diseases, **including but not limited to HIV/AIDS, Tuberculosis, COVID-19 and other emerging infectious and neglected diseases.**

Recognizing that bilateral, multilateral and international cooperation among scientists, public health officials and education and advocacy specialists in India with counterparts throughout the world could meaningfully contribute to, and benefit from, the development of new and improved biomedical tools and

technologies to prevent and treat such diseases of concern; the Parties intend to consider opportunities to co-operate, and are willing to contribute their experience and resources for research and development of vaccines and other new, improved and innovative "biomedical tools and technologies" ("**Products**")[1] for HIV, TB, emerging infectious diseases and other global health threats.

Thus, the Parties agree to restate their shared objective, and extend their partnership through this Tripartite Memorandum of Understanding for a period of five years effective from the date of signing of thisMOU.

IT IS HEREBY AGREED

1. Objectives

Subject to the terms hereof, the Parties confirm by this Tripartite Memorandum of Understanding that they propose to participate and collaborate to prevent, diagnose and/or treat diseases of concern in India and globally, including HIV, Tuberculosis, emerging infectious diseases like COVID-19 and other global health threats, across Product development including translational research, preclinical and clinical development, community engagement and socio-behavioural research, low cost manufacturing, public health access, etc. ("**Product research and development**")

Further, the Parties propose to substantially describe each bilateral or trilateral collaboration entered into under this MOU, specifically with IAVI as one of the Parties, in the form of a specific research project (each a "**Research Project**" and collectively "**Research Projects**") and enter into a specific Scope of Work ("**SoW**") for each Research Project executed by the Parties either directly or through their respective affiliates or institutes which, as relevant, may be put up for consideration of the Health Ministry's Screening Committee ("**HMSC**") as relevant. Each such SoW shall be read and interpreted as a part of this MOU, however, in the event that there is any conflict between this MOU and a Research Project's SoW, the SoW shall control.

The Parties understand and agree that the Research Projects and initiatives may be funded by various funding agencies and organizations and may be subject to different/additional requirements than those stated herein (including the obligation to disclose certain confidential information to funders). The Parties agree to use best efforts to address such issues in a project/initiative agreement that is specific to a project or initiative, and to accommodate all Parties' interest therein. In the event that there is any conflict between this MOU and a project/initiative agreement specific to a project or initiative, that project/initiative agreement shall control.

Furthermore, the Parties agree that each Party may individually enter in cooperative agreements with others in the public and private sectors to facilitate and participate in Product research and development, and thus agree that such independent agreements will not be read and interpreted as a part of this MOU.

2. **Cooperation**

It is anticipated that the joint efforts of the Parties may include, but not be limited to, the following:

2.1. Scientific conduct across different stages of Product research and development inclusive of preclinical, clinical trials (Phase 1,2 and 3), research, epidemiology and community preparedness, manufacturing, introduction, access, etc;

2.2. Technology and knowledge transfer for the development and evaluation of the Products;

[1] For the purpose of this document, biomedical tools and technologies are defined as interventions including, but not limited to vaccines, antibodies and other biotherapeutics

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2.3. Building of capacity and capability inclusive of training of human resources for conducting Product research and development activities;
2.4. Building partnerships across geographic areas, national and global, for conducting Product research and development activities;
2.5. Facilitating measures to ensure accessibility, uptake and distribution of the Products, inclusive of target product profile development, policy and regulatory facilitation, assessments, inter-ministerial stakeholder engagement etc.;
2.6. Funding or facilitating sustainable measures for carrying out Product research and development and access.

3. DBT and ICMR Facilitation

3.1. **Joint facilitation**

i. Co-funding Product research and development;
ii. Technology transfer, including but not limited to transfer of manufacturing technology for production of one or more successful candidate(s) developed through a development partnershipwith an Indian manufacturer;
iii. Partner selection, recommendation and access to establish partnerships for conducting Productresearch and development activities;
iv. Facilitating inter-ministerial stakeholder engagement to accelerate initiatives under this MOU, including promptly obtaining or granting necessary permits and permissions for carrying out Product research and development and access, transfer of products to and from India as per its laws, assuring harmonization of goals among its agencies and facilitating interactions between theParties, media and non-governmental organizations;
v. Facilitating regulatory science and policy support to ensure Product development, clinical trials,manufacturing, accessibility, uptake and distribution of the Products;
vi. Monitoring and management of activities being conducted, and partnerships being developedunder this MOU.

3.2. **ICMR Facilitation**

i. To conduct clinical trials as part of international collaboration.
ii. To promote and provide guidance on research governance issues, including ethical issues in medical and health research and inter-sectoral coordination.
iii. To facilitate advanced training in identified research areas in India and abroad.

3.3. **DBT Facilitation**

i. To establish one or more research partnerships to design, develop, manufacture and evaluate new and improved biomedical tools and technologies.
ii. To build capacity and capability for development, manufacturing, clinical testing of new and improved biomedical tools or technologies.
iii. To develop and validate (clinical trials) medical products including drugs, diagnostics, vaccines, devices and allied technologies jointly developed under this MoU

4. IAVI Facilitation

4.1. Co-funding Product research and development;
4.2. Technology transfer, inclusive of intellectual property rights, licenses, and rights to transfer technology to partners in India to support Product development, manufacturing and distribution

4.3. Contributing technical and management expertise and knowledge transfer to enable preclinical studies, clinical trials (Phase 1,2 and 3), CMC activities, site development, research, epidemiology, community preparedness, and regulatory strategy development;
4.4. Technical assistance and knowledge management support for building of capacity and capability, including but not limited to education, advocacy and training related to preparation for conducting different stages of Product research and development;
4.5. Undertaking activities to ensure accessibility, uptake and distribution of the Products in developing countries in sufficient quantities at a reasonable cost or license, inclusive of target product profile development, demand assessment etc.
4.6. Building partnerships across geographic areas, national and global, for conducting Product research and development activities

5. General Principles of DBT

DBT has a mandate of development and manufacturing of biomedical tools and technologies that may be using recombinant technologies and has been supporting programmes on all aspects of development of Products for different diseases including HIV, Tuberculosis, emerging diseases, neglected diseases and other diseases of concern for India.

6. General Principles of ICMR

Promotion and co-ordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information thereto.

7. General Principles of IAVI

IAVI seeks to develop and enable global access of novel and improved Products for HIV, Tuberculosis, emerging diseases, neglected diseases and other diseases of concern, through a variety of cooperative agreements.

8. Non- Exclusivity

The Parties shall pursue the objectives of this MOU on the basis of non-exclusivity. None of the Parties, nor their affiliates, employees or agents shall be restricted from making any arrangement or agreement with any third Party relating to activities to prevent, diagnose and/or treat diseases of concern in India and globally, including without limitation HIV, Tuberculosis, emerging infectious diseases and other global health threats, across Product development including translational research, preclinical and clinical development, community engagement and socio-behavioural research, low cost manufacturing, public health access, etc. and notwithstanding any similar or identical Product research and development undertaken by the Parties under this MOU. DBT or ICMR may solely or collaboratively make arrangement/agreement to any third party which does not necessarily require intervention of IAVI.

9. Monitoring and Evaluation

Parties agree to the setting up of a Joint Steering Committee ("**JSC**"), comprising equal number of representatives from all Parties. The Joint Steering Committee shall meet at least once a year and be responsible for:

9.1. Working out the details of implementation of this MOU;
9.2. Reviewing new Research Project/s under this MOU and facilitating institutional approvals on their specific SoWs;
9.3. Monitoring and regulating SoWs under this MOU;
9.4. Defining the financial and administrative terms of cooperation; and
9.5. Arranging any supplementary agreements required.

10. Confidentiality

10.1. During the term of this MOU and for a period of five years thereafter, each Party, their affiliates, employees and agents shall not disclose any confidential information of the other Parties;

10.2. As among the Parties, each Party shall retain all its respective intellectual property rights;

10.3. No party shall make any public announcement relating to this MoU or relating to scientific research outcome and commercialization under this MOU or any of the collaborative work hereunder without the prior consent of the other Parties;

10.4. All information and documents to be exchanged pursuant to the MOU will be kept confidential by the Parties and will be used subject to such terms as each Party may specify. The Parties will not use the information for purposes other than that specified herein or in the relevant SoW or project/initiative agreement without the prior written consent of the other Parties;

10.5. All confidential information shall remain the exclusive property of the disclosing Party. The Parties agree that the disclosure of confidential information does not grant or imply any license, interest or right to the recipient/s in respect to any intellectual property right of the disclosing Party; and

10.6. Unpublished information, whether oral, in writing or otherwise, discovered or conceived by the scientists or technicians and exchanged under the provisions of this MOU will not be transmittedto a third party, unless otherwise agreed by the Parties in writing.

10.7. Confidential information referred to herein shall not include any information that: (i) was publicly known or made generally available without a duty of confidentiality prior to the time ofdisclosure by a disclosing Party to a receiving Party; (ii) becomes publicly known or made generally available without a duty of confidentiality after disclosure by a disclosing Party to a receiving Party through no wrongful action or inaction of the receiving Party; (iii) is in the rightful possession of a receiving Party without confidentiality obligations at the time of disclosure by a disclosing Party to a receiving Party as shown by the receiving Party's then- contemporaneous written files and records kept in the ordinary course of business; (iv) is obtained by a receiving Party from a third party without an accompanying duty of confidentiality and without a breach of such third party's obligations of confidentiality; or (v) is independently developed by a receiving Party without use of or reference to the disclosing Party's confidential information, as shown by written records and other competent evidence prepared contemporaneously with such independent development.

10.8. If a receiving Party becomes legally compelled to disclose any confidential information, the receiving Party will provide the disclosing Party prompt written notice, if legally permissible, and will use its best efforts to assist the disclosing Party in seeking a protective order or another appropriate remedy. If the disclosing Party waives the receiving Party's compliance with the confidentiality provisions of this MOU or fails to obtain a protective order or other appropriate remedy, the receiving Party will furnish only that portion of the confidential information that is legally required to be disclosed; provided that any confidential information so disclosed shall maintain its confidentiality protection for all purposes other than such legally compelled disclosure.

11. Term and Termination

11.1. This MOU shall enter into force on the date of its signing by the third and last Party and should remain in force for five years thereof.

11.2. This Memorandum of Understanding may be terminated by any Party upon 30 days' prior written notice or extended upon by a written agreement of all the Parties.

11.3. If any Party commits a material breach of this MOU, this MOU, or the Statement of Work to which the breach relates, may be terminated by the non-breaching Parties upon ninety (90) days' notice, if the breach has not been cured during that period, or, if such breach is only reasonably capable of being rectified within a longer time period, if the breaching Party has not taken and/or

does not continue to take all reasonable measures to rectify it.

11.4. No Party will be liable for any delay or failure in performing its obligations under this MOUto the extent such failure or delay is due to causes beyond its reasonable control; provided that such obligations are performed immediately upon the termination of such cause. If such failure continues for ninety (90) days or more, the other Parties may terminate this MOU immediately upon notice to the failing Party.

12. Compliance with Law

Each Party will perform its obligations under this MOU in compliance with all applicable national and local laws, policies and regulations of their respective countries. The ethical guidelines, exchange of biological materials and other activities hereunder shall be conducted as per the respective national laws and guidelines/regulations as issued from time to time in case of clinical trial, observational studies etc.

13. Intellectual Property Rights, Commercialization and Publications

Intellectual Property Rights:

13.1. The Parties shall ensure appropriate protection of intellectual property rights generated from cooperation pursuant to this MOU, consistent with their respective laws rules and regulations and multilateral agreements to which countries of the Parties are party to.

13.2. In case of research results obtained through joint activities, the grant of intellectual property rights will be sought by the relevant Parties jointly and once granted these rights will jointly beowned by the Parties.

13.3. No Party shall assign any rights and obligations arising out of the intellectual property rights generated pursuant to the cooperation activities under this MOU without prior written consent of the relevant co-owning Party/ies. DBT & ICMR can own the IPR Rights jointly, however, IAVI can claim only if it takes partin financial facilitation of those R&D activities.

Commercialization:

13.4. **In case of research results obtained through joint activities under this MOU, any future commercialization activities, including the respective roles and responsibilities of the Parties, shall be mutually agreed upon under a separate agreement to be entered by the Parties.**

Publication:

13.5. 13.5 Any publication, document and/or paper arising out of joint work conducted by the participants pursuant to this MOU must acknowledge the Parties responsible and will bejointly owned by the said Parties.

13.6. The use of the name, logo and/or official emblem of any of the Parties on any publication, document and/or paper shall require prior permission of the owning Party. Without limiting the foregoing, no Party shall misuse the official emblem and logo of any other Party.

14. Data and Reports

Any data and reports generated under any Research Project will be jointly owned by the Parties of the Research Project. Each Party will have the right to use and reproduce such data and reports in a manner consistent with this MOU and the applicable Research Project objectives after receiving consent from the other Party/ies, such consent not to be unreasonably withheld or delayed.

15. Disputes

Any dispute arising out of the interpretation or implementation of this MoU shall be settled amicably through consultation and negotiations between the Parties

16. Notices

Any communication pursuant to this MOU must be in writing and, unless otherwise stated, may be given in person or by email or speed post/courier services as follows (or to any other address given on five (5) days' notice to the other Party) and will be deemed to be given at the time of delivery:

a) To DBT:

Department of Biotechnology
6th-8th Floor,
Block 2 CGO Complex,
Lodhi Road New Delhi - 110 003

Attention:

a. Head, Medical Biotechnology-III Division (Infectious Disease Biology)

b) To ICMR:

Indian Council of Medical Research
Ramalinga Swami Bhawan,
P.O. Box No. 4911,
Ansari Nagar West,
New Delhi – 110029.

Attention:

a. Head, Division of Epidemiology and Communicable Diseases, ICMR Hqrs / Program Officer, HIV Vaccine Program

c) To IAVI: International AIDS Vaccine
Initiative Inc.Plot No. 4, Factory Road,
Near Chattisgarh Sadan,
Opp. Safdarjung Hospital,
Ansari Nagar West,
New Delhi – 110029.

Attention:

a. Country Director (rgoyal@iavi.org), for all invoices, financial reporting and technical or operational communications under this MOU.
b. General Counsel (generalcounsel@iavi.org), in connection with contractadministration or amendment under this MOU.

17. Legal Status of Memorandum of Understanding

The Parties agree to understand that, except for clauses 10 and 13, this MOU shall not create or give rise to any legal binding obligations upon the Parties and all agreements and obligations contemplated by this MOU are subject to entering into a separate agreement.

If any term of this MOU is or becomes illegal, invalid or unenforceable in any jurisdiction, that will not affect the legality, validity or enforceability in that jurisdiction of any other term of this MOU or the legality, validity or enforceability in other jurisdiction of that or any other term of this MOU. The Parties will use their reasonable efforts to substitute for the invalid or unenforceable term with a valid and

enforceable term which conforms as nearly as possible to the original intent of the Parties.

This MOU represents the entire understanding among the Parties relating to the transaction/s contemplated by this MOU and supersedes all previous understandings, representations or MOUs, relating to such transaction/s. No amendment or waiver of any term of this MOU will be deemed effective unless in writing and signed by all Parties.

[*Signature page follows.*]

IN WITNESS WHEREOF, the undersigned being duly authorized representatives of the respective Parties have signed this MOU inthree originals, each in the English and Hindi language, both texts being equally authentic. In case of anydivergence in interpretation, the English text shall prevail.

Department of Biotechnology	**Indian Council of Medical Research**	**International AIDS Vaccine Initiative Inc.**
By:	By:	By:
Name: Dr Rajesh S Gokhale Title: Secretary, Department of Biotechnology	Name: Prof. Balram Bhargava Title: Secretary, DHR & Director-General, ICMR	Name: Dr. Mark Feinberg Title: President and CEO
Date: Feb 15, 2022 Place: New Delhi, India	Date: Feb 24, 2022 Place: New Delhi, India	Date: 2/2/2022 Place: PHILADELPHIA, PA USA