

MEMORANDUM OF UNDERSTANDING (MOU)

**Between
Indian Council of Medical Research (ICMR)
And
International AIDS Vaccine Initiative (IAVI)
on cooperation in AIDS Vaccine Development**

This MOU is between:

INDIAN COUNCIL OF MEDICAL RESEARCH, 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 P.B. No.4911, Ansari Nagar, New Delhi, India- 110029 (**ICMR**).

AND

INTERNATIONAL AIDS VACCINE INITIATIVE, 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 (**IAVI**).

IAVI: IAVI's mission is to ensure the development of and access to safe, effective, accessible, preventive, AIDS vaccines for use throughout the world. IAVI's scientific agenda is focused on identifying the most promising candidate for AIDS vaccines and accelerating the development of such vaccines for licensure and distribution in the developing world where the epidemic is the greatest. IAVI has collaborations with national and international programs in AIDS vaccine development and is recognized as an UNAIDS Collaborating Center for AIDS Vaccine Development.

ICMR: ICMR is the apex body in India for the formulation and coordination 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. While several of the ICMR institutes are engaged in HIV/AIDS related research, its National AIDS Research Institute (NARI), located in Pune had been designated as the apex technical body for research and development in HIV/AIDS in the country.

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

WHEREAS

It is recognized that HIV/AIDS is a Global Public Health priority. The disease continues its insidious spread throughout the world, and particularly in the developing world where over 95% of

new HIV infections occur. It is anticipated that Asia will face the greatest burden of new HIV infections, with India being particularly vulnerable.

Recognizing that bilateral, international and multilateral cooperation among scientists, public health officials, and education and advocacy specialists in India with counterparts within and throughout the world would benefit from the development of new and improved HIV/AIDS prevention programs and technologies.

ICMR and IAVI are willing to collaborate and contribute their experience 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 and other Biomedical tools for prevention of AIDS based on mutual agreement and thus wish to enter into an MOU for five years from the Effective Date in accordance with the terms of this MOU.

HAVE REACHED THE FOLLOWING UNDERSTANDING:

1. Objective Of The Parties

Subject to the terms defined here, the Parties confirm by this Memorandum of Understanding that they propose to collaborate on AIDS Vaccine development and evaluation of one or more safe and effective AIDS vaccines primarily for use in, but not limited to, India and other Biomedical tools for prevention of AIDS based on mutual agreement. Furthermore, the parties propose to substantially describe each collaboration in the form of a specific research project/s (each a **Research Project** and collectively the **Research Projects**) and enter into a specific Statement of Work (the **Program**) for each of the Research Project/s executed by the Parties either directly or through its affiliates or institutes which shall be put up for consideration of Health Ministry's Screening Committee (HMSC)

2. Modes of Cooperation

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

- Establish (by linking investigators within and outside India, with clinical researchers located at sites within India, capable of undertaking clinical trials of AIDS vaccines) one or more partnerships to design, develop and evaluate one or more candidate AIDS vaccine appropriate for use in but not limited to, India.
- Building of Site, Community, Epidemiology and Research Preparedness capacity, including education, advocacy and training related to preparation for conducting vaccine development and clinical testing of AIDS vaccines in India and other Biomedical tools for prevention of AIDS.
- Conducting Phase – I, II and III trials of AIDS vaccines in India.
- Facilitate the provisions to ensure accessibility, uptake and distribution of AIDS vaccines in India.

3. Monitoring and Evaluation:

ICMR and IAVI are intended to develop strategic plans for collaboration and to facilitate the expedited review and clearance of meritorious projects and other activities. Both the parties would form a Joint Monitoring Committee (JMC) which should include representatives from each party. This JMC should meet at least once a year and designate a Secretariat that maintains regular communication and undertakes joint activities throughout the year.

4. Terms And Termination

- a) This MOU becomes operative on the date of its signing and should remain operative for five years.
- b) The MOU is not intended to create binding or legal obligation between the parties.
- c) The MOU will be subject to renewal only by the mutual agreement of the Parties.
- d) If either 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 Party 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.
- e) Neither Party will be liable for any delay or failure in performing its obligations under this MOU to 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 Party may terminate this MOU immediately upon notice to the failing Party.

5. Non-Exclusivity

The parties shall pursue the objectives of this MOU on the basis of non-exclusivity. Neither the parties, nor their affiliates, employees or agents shall be restricted from making any arrangement or entry into any agreements with any third party for direct or indirect participation in support of, or contribution to AIDS Vaccine development. Without limitation on the forgoing, ICMR may negotiate directly with any third party and not necessarily through IAVI.

6. Compliance With Laws

Each Party will perform its obligations under this MOU in compliance with all applicable national laws, policies and regulations of their respective countries. The ethical guidelines, exchange of biological material may be followed as per the respective national laws and guidelines /regulations as issued from time to time in case of clinical trials, observational studies etc.

7. Confidential Information

Either Party may disclose to the other, proprietary information that relates to this MOU (the **Confidential Information**), subject to the other provisions of this Section. All Confidential Information disclosed by a Party under this MOU will be maintained in confidence and otherwise safeguarded by the receiving Party.

8. Publications and Intellectual Property Rights

- i. Both parties agree to ensure appropriate protection of Intellectual Property Rights generated from such cooperation consistent with their respective laws, rules and regulations and other international agreements to which both parties are signatories.
- ii. In case research is carried out solely and separately by the Party or the research results are obtained through the sole and separate effort of the Party, the Party concerned alone will apply for grant of IPR and once granted, the IPR will be solely owned by the concerned Party.
- iii. In case of research results obtained through joint activities, the grant of intellectual property rights will be sought by both the parties jointly and once granted these rights will jointly owned by the parties
- iv. Any publication, document and/or paper arising out of joint work conducted by the Parties pursuant to this MoU will be jointly owned. The use of the name, logo and/or official emblem of the Parties on any publication, document and/or paper will require prior permission of both the Parties. It may however be ensured that the official emblem and logo is not misused.

9. Data And Reports

All data and reports generated under any Research Project will be jointly owned by the Parties. 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, such consent not to be unreasonably withheld or delayed.

10. 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) If to IAVI, to: Address: International AIDS Vaccine Initiative
F-2-A, Second Floor, The Mira Corporate Suites,
Plot 1 & 2, Ishwar Nagar, Mathura Road, New
Delhi-110065, INDIA

Attention: Country Director, for all invoices, financial reporting and technical or operational communications under this MOU.
General Counsel (generalcounsel@iavi.org), in connection with contract administration or amendment under this MOU; and

(b) If to ICMR, to:

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

Attention: Head, Division of Epidemiology and Communicable Diseases,
ICMR Hqrs, / Program Officer, HIV Vaccine program

11. Legal Status of Memorandum of Understanding

The Parties agree to understand that this Memorandum of Understanding shall not create or give rise to any legal binding obligations upon the parties and all agreements and obligations contemplated by this Memorandum of Understanding are subject to entering into an agreement.

If the 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 MOU between the Parties relating to the transaction contemplated by this MOU and supersede all previous understandings, representations or MOUs, relating to that transaction. No amendment or waiver of any term of this MOU will be deemed effective unless in writing and signed by both Parties.

IN WITNESS WHEREOF, the Parties hereto have caused this MOU to be duly executed by their authorized representatives:

This MOU is signed at -----on ----- with two originals, each in English and Hindi language, both texts being equally authentic. In case of any divergence in interpretation, the English text shall prevail.

International AIDS Vaccine Initiative

Indian Council of Medical Research

By:

By:





Name: Margie McGlynn

Name: Dr. V.M.Katoch,

Title: CEO and President

Title: Secretary, Department of Health Research and Director General, ICMR

Date: 10/15/2014

Date: 10 NOV. 2014 at New Delhi