



Renewal of MoU between ICMR and Inserm

Reference to Article 9 of the Memorandum of Understanding signed on March 10th, 2018 between ICMR and Inserm - attached to this document, we hereby agree for its renewal under the same conditions and provisions, for further period of 4 years, effective from the date of March 10th, 2022.

Signed in two original copies.

For Inserm

Dr Gilles Bloch CEO and Chairman

Inserm

Paris, France

Date:

2 5 MAI 2022

For ICMR

Balran Blaga

Prof. Balram Bhargava

Director General

ICMR-

New Delhi, India

Date: 4th May, 2022



Liberté Égalité Fraternité



La science pour la santé ______ From science to health

Department of National and Foreign Affairs

International Relations Agnès Kergus International Affairs Officer

Reference: 2022/ AK-YM

Dr Mukesh Kumar Head International Health Division ICMR India

Paris, 7 June 2022

Subject: Extension of our Inserm-ICMR Memorundum of Understanding (MoU)

Dear Dr Kumar,

As agreed, please find attached one original copy of the letter for extension of our Inserm-ICMR MoU signed by our Chairman and CEO.

Regards,

Agnès Kergus

Mational de la Santé
Mational de la Santé
Médicale
101. rue de Toibiec
101. rue de Toibiec
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101. rue de Toibiec

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Roceived from INSERM, Paris after signature for renewal of
ICMR-INSERM MOU for 4 yrs web 10/3/2022.

for information please

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MEMORANDUM OF UNDERSTANDING

BETWEEN

THE INDIAN COUNCIL OF MEDICAL RESEARCH, REPUBLIC OF INDIA

AND

THE NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH,

FRENCH REPUBLIC

Memorandum of Understanding (MoU) between The Institut National de la Santé et de la Recherche Médicale (National Institute of health and medical research), hereinafter referred to as Inserm, a public institution of scientific and technological vocation located at 101-Rue de Tolbiac-75013, Paris, France.

and

The Indian Council of Medical Research (ICMR), hereinafter referred to as ICMR, a medical research body for the formulation, coordination and promotion of biomedical research, funded by the Government of India through the Department of Health Research, Ministry of Health & Family Welfare located at V.Ramalingaswami Bhawan, Post Box No. 4911 Ansari Nagar, New Delhi – 110029, India.

Hereinafter together referred to as "the Parties", and separately referred to as "the Party".

Considering the succesful progress made in research partnership between ICMR and Inserm under the previous agreement signed on February 1st 1989 and the will of both Parties to strengthen their relations within the framework of the international scientific and technological cooperation and to promote their cooperation in fields of mutual interest;

Agree to promote collaborative efforts under the following terms:

Article 1 Purpose and areas of cooperation

The Parties wish to set out and agree the terms and conditions of cooperation in areas of common interest within the medical, life sciences and health research fields. Based on scientific excellence on both sides, the Parties agree to have a specific focus upon:

- Diabetes & Metabolic disorders:
- Bioethics with focus on Ethics &-regulatory issues of Gene editing techniques;
- Rare diseases;
- Any other areas of mutual interest can be considered after discussions between the Parties.

Article 2 Modalities of cooperation and commitments

The terms and conditions of cooperation for each activity to be implemented under this MoU shall be mutually discussed and agreed upon in writing by authorized representatives of both institutions prior to the initiation of that activity, through separate agreements, covering specific fields of collaboration, the treatment of intellectual property rights, confidentiality rules, liability, their financing mode and other appropriate matters for implementation of the cooperative activities under this MoU.

As both institutions are aware of existing limitations in their respective budgets, they will, as a rule, not enter into financial commitments that reach beyond their limits.

2.1 - International Research Network in the field of Diabetes & Metabolic disorders The development of an International Research Network will be based on the International Associated laboratories (IAL)signed in 2013 and renewed in 2017 for 4 years with the support of Inserm and Institute of Liver and Biliary Sciences (ILBS).

The scientific purpose and the content of this networking project will be jointly discussed and their general principles will be validated before their implementation. Two (2) scientific coordinators will be respectively nominated by both Parties. They will be in charge of preparing a detailed proposal that will be submitted to each Party for evaluation and approval.

The Parties shall endeavor, according to their available budget, to support the participation of Indian and French researchers to this International Research Network. Any other potential sources of funding, especially through the European and IFCPAR mechanisms, might be approached and sought by the scientific researchers.

2.2- Ethics & regulatory issues of Gene editing techniques

Cooperation in the field of Bioethics with focus on Ethics and regulatory issues of Gene editing techniques such as need for initiatives to increase knowledge base, capacities, funding, guidelines, inter agency communications and interactions, engagement with public and other stakeholders, establish science communication and to foster research to assess the feasibility, efficacy and safety of CRISPR technology will be promoted by the Parties(based on the outcomes of joint workshop "Ethical and scientific issues of gene editing using CRISPR-CAS 9 technology Cooperation" organized in India in April 2017), according to their available budget, through exchanges of information and workshops.

2.3 - Rare diseases

Inserm and ICMR will think about the best ways to foster, through different tools, the cooperation of their respective teams in the field of Rare diseases.

2.4 - Joint scientific seminars and workshops

After identifying the specific scientific topics within the common interest fields as identified under Article 1 scientific seminars or workshops involving a small number of experts of both parties (between 6 and 10 from each side) could be organized to deepen a field of interest. The seminars or workshops will be organized in France or in India.

Each party will cover the costs of travel of its own researchers, students (masters or doctorates) and experts while the hosting party will take care of the local organization of the event and help participants' accommodation cost (per day).

2.5 - Other collaborative actions

Other collaborative actions in the three (3) fields of cooperation identified could be foreseen, according to their scientific importance and mutual interest and according to the general objectives of this MoU.

Article 3 Human resources management

3.1 - Employer liability

Each Party's beneficiaries shall be and remain at all times its employees (meaning that each Party's beneficiaries must benefit from a work contract and a salary provided by their home institution during their stay in each hosting institution). The hosting Party shall never be employer of the other Party's beneficiaries and shall in no case be liable to pay for salaries, wages, pensions, superannuation, statutory leave, or any other employee entitlement of the other Party's beneficiaries during their stay at the hosting institution.

3.2 - Health insurance

Each Party shall ensure that its beneficiaries will benefit from appropriate health insurance while on assignment at the hosting institution. Inserm's beneficiaries benefit from contractual specific assignment health insurance. The overseas mediclaim insurance cover should be taken care of by ICMR's beneficiaries.

3.3 – Hosting institution regulations

The beneficiaries shall be informed by the person in charge of their supervision at the hosting institution of specific regulations of this hosting institution (internal regulations of the hosting structure, in particular regarding modalities and hours of access to workplace and health and safety; terms of use for access to hosting structure computer resources and Internet services; code of ethics in force; etc.). Each Party shall commit to assure respect of these regulations by their beneficiaries while at the hosting institution.

Article 4 Confidentiality

The Parties agree on the following principles which may be further developed, with the agreement of the Parties, by separate agreements referred to in Article 2.

- A. (i) Each Party shall commit, in its name and on behalf of its beneficiaries, to consider as confidential information of any type that it will gather during exchanges with the other Party.
 - (ii) The Parties will freely exchange information within the framework of this MoU, with the exception of such cases where the national legislation or the Party providing such information, has set restrictions on its use or disclosure.
 - (iii)Under no circumstances, restricted information will be transferred by either Party to a third party, without prior written consent of the other Party.
 - (iv)The information resulting from the activities from implementation of the Agreement/MoU, will be published or divulged to third Parties, only with prior written consent by the other Party.
- B. The following information will however not be considered as confidential:

Notwithstanding with the above, any information which falls within one of the following shall not be Confidential Information:

- a) Information that had been already in the public domain when obtained from the other, or information that has come into the public domain after being obtained from the other party due to reason not attributable to the receiving party;
- b) Information properly obtained from a third party without bearing confidentiality obligations;
- c) Information that had already been obtained at the time when the information was obtained from the other party;
- d) Information that was developed independently not from information obtained from the other, and which fact can be proved in writing; and
- e) Information the disclosure of which is obligatory under the laws or court orders.

This obligation of confidentiality will remain in force during this MOU and five (5) years after its term or termination.

Article 5 Intellectual Property Rights and Commercialization

The Parties agree on the following principles which may be further developed, with the agreement of the Parties, by separate agreements referred to in Article 2.

Each Party shall remain the owner of the results of its work performed out of the framework of this MoU, or obtained without contribution of the other Party.

Any collaboration implemented in the framework of this MoU shall be subject to signature of a specific agreement detailing the defined work results intellectual property scheme.

- 5.1 The Parties shall ensure appropriate protection of Intellectual Property Rights generated from cooperation pursuant to MoU, consistent with their respective laws, rules and regulations and multilateral agreements to which both Parties are party to.
- 5.2 In case of research results obtained through joint activities with the contribution of each Party, these research results and all intellectual property rights resulting therefrom (hereinafter "Joint Result(s)") shall jointly be owned by the Parties, and be consistent with relevant national laws of the Parties (and, for Inserm, subject to third parties rights understanding that Inserm laboratories have other parent organizations).
- 5.3 On a case-by-case basis, the Parties shall agree to designate one of them to take the primary responsibility relating to patent protection and licensing of the Joint Result, with the full assistance and cooperation of the other Party. The Parties agree to designate the Party with the most knowledge and expertise in the subject matter of the Joint Result (hereinafter "the Leading Party"). The Leading Party shall consult with and keep the other Party fully informed of important issues relating to the protection and licensing for which it is responsible and shall furnish to the other Party copies of all relevant document.

For each Joint Result, the Parties shall conclude a co-ownership agreement which shall designate the Leading Party, specify the role and tasks of the Leading Party as regards patent filing, prosecution, maintenance of patents, licensing and exploitation of the Joint Result and shall provide for a fair and equitable sharing of patent costs and revenues issued from the exploitation of the Joint Result.

Unless the terms of the co-ownership agreement are agreed, no Party may either grant a license or assign its interest in a Joint Result to any third party without the prior written consent of the other Party and in compliance with the relevant national laws of the Parties.

Article 6 Publication and communication – Use of name

The Parties agree on the following principles which may be further developed, with the agreement of the Parties, by separate agreements referred to in Article 2.

- (i) Publications and communications on work implemented in the framework of this MoU shall be decided by common joint agreement, when relevant, and in accordance with both Parties' policies.
- (ii) Any publication, document and/or paper arising out of joint work conducted by the participants pursuant to this MoU must acknowledge the ICMR- Inserm Partnership.
- (iii) Each Party undertakes not to use, in writing or orally, the name of the other Party or any of its personnel for any purpose whatsoever, regardless of the medium used, without the prior written consent of the Party concerned.

The use of 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.

Article 7 Ethical issues/Transfer of biological material/Data sharing

Both Parties acknowledge the importance of the protection of human and animal subjects in any health program. In recognition of this, both the Indian and the French governments have adopted laws and regulations on the protection of human and animal subjects, including the transfer of biological material and intend to follow the same in accordance with applicable laws, regulations and policy of each country. Matters related to biological material shall be dealt with in accordance with the extant laws, rules and regulations of each Party.

Investigators should also share their findings with the relevant institutions articulating how the work informs policy and practice both in India and France. The Parties encourage the investigators to put the data arising from the funded work into open access.

Article 8 General liability - Insurance

Each Party shall maintain all appropriate insurances to cover its obligations under this MoU. It is recalled that Inserm, as a public institution, is its own insurer, unless it is legally required to take out insurance (such as health insurance, insurance for biomedical research, vehicle insurance).

Each of the Parties will be liable, under the provisions of local laws and regulations, for any harm or injury caused to the other Party or to third parties on the occasion of performance of this MoU, including harm or injury resulting from the use of materials or equipment placed at the disposal to the other Party.

Article 9 Term – Renew – Modifications

This MoU shall come in to force from the date of its signature by the Parties and shall remain in force for a period of 4 years, thereafter it shall be extended by written consent of the Parties.

This MoU may be amended at any time by mutual written consent of the Parties. It shall enter into force on the date of its signature thereof by the Parties.

Article 10 Termination

10.1 The MOU may be automatically terminated by a Party if the other Party fails to perform one of its obligations under this MOU. This termination will only become effective one (1) month after the requesting Party has sent a registered letter with acknowledgement of receipt specifying the motivations for said complaint, unless the defaulting Party has, within this period, fully satisfied its obligations or brought the evidence of an impediment due to a force majeure event.

Each of the Parties shall be excused for not fulfilling its obligations, and may not be held responsible or liable to pay damages vis-à-vis the other Party, if the failure to perform is due to a force majeure. The Party being unable to perform its contractual obligations as a result of a force majeure event shall immediately notify the other Party in writing. If this inability to perform or delay in the performance due to a force majeure event continues beyond a period of three (3) months as from this notification, said other Party shall be entitled to terminate automatically the MOU at any time by way of a written notification sent to the other Party.

The exercise of this right to terminate the MOU does not exempt the defaulting Party from the obligation to meet the obligations undertaken until the date on which the termination becomes effective and this, without prejudice to the damages sustained as the case may be by the complaining Parties as a result of the early termination of the MOU.

10.2 Either Party may terminate the MoU by giving a written notice of its intention to terminate to the other Party ninety (90) days in advance.

10.3 In the event of the early termination of the MOU for any reason whatsoever, or upon the expiry of the term of the MOU, the provisions relating to confidentiality (Article 4), communications and publications (Article 6), intellectual property (Article 5), as well as to applicable law and dispute resolution (Article 11) shall remain effective till the completion of the ongoing joint projects under the MoU.

11 Dispute resolution

Any dispute that may arise between the Parties with regard to the interpretation or implementation of this MOU, the Parties will first attempt to resolve their differences amicably, through negotiations between the Parties.

To initiate conciliation, a Party must give notice, in writing to the other Party, requesting conciliation in accordance with this clause. Within thirty (30) days after this notification, the Parties shall try to appoint a single conciliator, but in the absence of agreement, each Party shall appoint one conciliator. The mission assigned to the conciliator(s) by the Parties is to suggest a solution in order to resolve amicably such dispute within sixty (60) days after the notification. For any claims subject to, but not resolved by, the conciliation pursuant to the stipulation hereinbefore defined, the claim will be resolved by litigation in a court of competent jurisdiction.

IN WITNESS WHERE OF, the undersigned, duly authorized thereto by the respective Parties, have signed this MoU.

Signed in New Delhi, on the 10th day of March, 2018 in two originals, each in the English and Hindi languages, both texts being equally authentic. In case of any divergence in interpretation, the English text shall prevail.

For the Indian Council of Medical Research:

Preet Sudan Secretary, DHR & DG, ICMR For the Institut National de la Santé et de la Recherche Médicale :

Pr Yves LEVY CEO and Chairman