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# Memorandum of Understanding for Academic Research & Development

This Memorandum of Understanding (MOU) is made and executed on this day of  $10^{th}$  September 2020.

#### BY AND BETWEEN

TMC-ACTREC, Mumbai having address at TMC-ACTREC, Paymaster Shodhika, Sector 22, Kharghar Navi Mumbai - 410210 (hereinafter referred to as "TMC-ACTREC" which expression shall unless it be repugnant to the context or meaning thereof be deemed to include its successors and permitted assigns) of the FIRST PART;

AND

Mahatma Gandhi Mission Institute of Health Sciences through its Constituent Unit the Mahatma Gandhi Mission's Medical College & Hospital, having address at Plot No. 1 & 2, Sector-1, NH-4 Junction, Kamothe, Navi Mumbai, PIN 410209

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25 SEN 2020, जोडगब - २/ Annexure -II होक विक्री नॉरवही शनु-क्रमाय १५१९ 0 . हि. ..... इस्ताचा प्रकार दस्त मोडणी करणात आहे । का हम. जी. हम नो Band. का तेज. भिरुकतीचे थोडबक्ता पर्णनं ..... महाक विकत पंजा यह विकास वाली इस या पशकारिय नाव... मुद्राप्त भूत्वा स्वयंत्रा ......... मिर्वे कार कार कार पाडे रेटेव वंडर, फटवाली पन्दाना मुद्देश विक्रेन्य भी तुकान नं. ती १, सेक्टर ३ई/ए, करवाती. जि. सवगड सही पादाना अक्षा वसेच प्रशेष्ट विकास है विकास है पता पत्वानाक, ६/१९१६-९७ 2 2 SEP 2020 ज्या बारणस्तारा ज्यांना कृतक संर्था येना त्यांनी त्यांच कारणासाठी . मुटांक खंखी केल्यापासुन ६ महिल्यात वापरणे बंधनकारक आहे. THE P or Dean. M.G.M. Medicar . . . . 3 Hospital 600016 incomment income

(hereinafter referred to as "MGMIHS/MGMMCH" which expression shall unless it be repugnant to the context or meaning thereof be deemed to include its successors and permitted assigns) of the SECOND PART;

WHEREAS the Tata Memorial Centre (TMC) is a fully funded Government-in-Aid institution of Department of Atomic Energy situated at Parel, Mumbai-400 012, the TMC-ACTREC (Advance Centre for Treatment, Research and Education is the state-of art R & D Satellite of TMC hereinafter referred to TMC-ACTREC.

WHEREAS the Hematopathology Laboratory at ACTREC is studying the immune cell profiling and serum cytokine levels in peripheral blood by Flow Cytometry as well as interaction of inflammatory proteins and their levels in mucosal cells from the nasal/oral swab using molecular techniques such as PCR in COVID-19 patients jointly with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.

**AND WHEREAS** MGMMCH having the required infrastructure, expertise and facilities, has been designated as a COVID hospital/center **and permitted** to test, admit and treat the COVID-19 patients.

AND WHEREAS THE TMC-ACTREC has approached the MGMIHS with a proposal and sought the COVID 19 patient data available with the MGMMCH. The said data will be used to carry out collaborative joint activities/research studies. MGMMCH after due consideration of the proposal, the importance of the research activities to the general public health and well being and considering the urgent need and requirement to undertake the activity, has agreed to participate in the activity.

AND WHEREAS the collaboration among the two institutions will provide a unique opportunity to determine immune cell subsets levels, inflammatory serum cytokine levels and proteins related immune response from nasal/oral mucosal membrane as well as their kinetics with SARS-CoV-2 infection status and COVID-19 disease progression over the infection period. The parties are aware that a successful study will develop the unique immune-cell signature specific to the pathogenesis COVID-

19 disease and its severity, which will eventually help and assist in better management of COVID-19 patients.

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AND WHEREAS the ICMR is a sponsor of this study. TMC-ACTREC and MGMMCH have authorized Covid-19 ward for the treatment of COVID-19 patients and hence, both institutions are collaborating as a part of ICMR Immunoprofiling Consortium for Covid-19.

AND WHEREAS the parties are interested and intend to focus on joint research activities relating to the multi-dimensional in-depth evaluation of immune-cell subsets and inflammatory cytokine levels using multicolor flow cytometry to develop an immune-cell signature as well as mucosal immune-response related proteins which will allow to study the severity and prognosis of disease in COVID-19 patients.

AND WHEREAS the Hematopathology Laboratory at TMC-ACTREC has an expertise of multicolor flow cytometric immunophenotyping and has developed a multi-dimensional immune-cell profile assay and cytokine assays and has a state-of-the-art flow cytometry facility and has experience in various immunological studies in human subjects.

AND WHEREAS the TMC-ACTREC and MGMMCH have decided to collaborate and to do jointly a research project to study the multi-dimensional in-depth evaluation of immune-cell subsets and inflammatory cytokine levels using multicolor flow cytometry to develop an immune-cell signature as well as mucosal immune-response related proteins which will allow to study the severity and prognosis of disease in COVID-19 patients.

AND WHEREAS patient's samples collected under this study will be used (after obtaining the required patient consents) for above mentioned COVID-19 related research studies only.

NOW THIS MOU WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:





# WORK RESPONSIBILITIES:

# (A) RESPONSIBILITIES OF TMC-ACTREC

- TMC-ACTREC's Hematopathology Laboratory shall do the multicolor flow cytometric immunophenotyping and cytokine assays in peripheral blood and study of nasal/oral mucosal proteins in COVID-19 patients jointly with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.
- TMC-ACTREC's Hematopathology Laboratory shall provide the vacutainers to collect peripheral blood and nasal/oral swab collection kits to MGMMCH and transport facility of these samples from MGMMCH to TMC-ACTREC.
- 3. The patient's details, samples and the data of research conducted will be safely stored in TMC-ACTREC and will be shared with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.
- **4.** TMC-ACTREC will share the results of the study with MGMMCH after completion of the project.
- TMC-ACTREC will not share this data with anyone other than Indian Council of Medical Research (ICMR) and ICMR Immunoprofiling Consortium.
- 6. TMC-ACTREC will share a part of patient's samples with Narayana Nethralaya Foundation (NNF), Bangalore which is a member of ICMR Immunoprofiling (IP) consortium.
- 7. TMC-ACTREC will allow the post-graduate students (maximum two students in a day) from MGM to observe the processing and analysis performed as a part of this study.

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# (B) RESPONSIBILITIES OF MGMMCH

- MGMMCH shall enroll patients with SARS-CoV-2 infection and will collect peripheral blood and nasal/oral swabs at time points as specified in the project proposal. MGMMCH will keep follow up as required by project proposal.
- 2. MGMMCH will share all the clinical and treatment details of the patients enrolled in this study as and when required by TMC-ACTREC.
- MGMMCH will not use any of the data provided by TMC-ACTREC for any other purpose/publication without obtaining prior written permission from Hematopathology Laboratory, TMC-ACTREC.

#### B. PUBLICATION POLICY:

- 1. Any publication resulting from this work will have authorship from all the two participating institutes and members of ICMR Immunoprofiling (IP) consortium depending upon the contribution in particular aspect.
- 2. Dr. Prashant Tembhare from TMC-ACTREC and Dr. Shilpi Sahoo from MGMMCH will have the authority to decide the authors of their respective groups which will be in accordance with the contribution of the authors.

#### C. REPORTING:

The Institutional Ethics Committee (IEC) of the parties hereto shall have the authority to evaluate effectiveness and adherence to the agreement and the periodicity of evaluations every year.

#### D. FUNDING:

1. Funds will be mainly required for vacutainer tubes and nasal/oral swab collection kits and transportation of the patient's samples from MGMMCH to TMC-ACTREC. TMC-ACTREC will provide vacutainer tubes, nasal/oral swab collection kits and personal protection equipment (PPE) kits required for this study to MGMMCH. TMC-ACTREC will transport the patient's samples from

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MGMMCH to TMC-ACTREC. Data storage infrastructure at **TMC-ACTREC** will be used for managing the data related activities. Hence for any partner storage of data will be done by individual partner's own fund.

The study is funded by ICMR as a part of Immunoprofiling (IP) consortium for COVID-19.

## E. CONFIDENTIALITY AGREEMENT:

The parties hereto acknowledge that, in the course of their activities under this MOU, it may be necessary for one party to provide documentation, technical and/or intellectual property to the other party. All Confidential Information provided or disclosed by either party hereunder shall remain the property of the furnishing party, and shall be held in strict confidence by the receiving party, its officers, employees, agents and all concerned persons unless the furnishing party otherwise consents in writing or unless disclosure of such Confidential Information is required by law. This clause will survive for five years the expiry of the MOU.

#### F. FINALITY:

This Memorandum of Understating embodies the entire agreement and understanding between the parties hereto relating to the subject matter hereof and there are no understandings, agreements, conditions or representations, oral or written, expressed or implied, with reference to the subject matter hereof that are not merged herein or superseded hereby. No modification hereof shall be of any force or effect unless reduced to writing and signed by the parties claimed to be bound thereby.

### G. TERM AND TEMINATION:

This MOU shall become effective from the later date of execution hereof and will remain in effect until 10/9/2022 unless modified or terminated by giving one month advance written notice by either party.

### H. SUCCESSORS AND ASSIGNMENT:

None of the parties hereto shall assign their rights or obligations under this Memorandum of Understanding to any third party or parties without the prior written consent of the other party. The provisions of this Memorandum of Understanding shall inure to the benefit of, and shall be binding upon, the successors and permitted

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assigns of the parties hereto. Succession/transfer of this project related data shall not be done without the written consent of the other party and the ICMR approval.

#### I. SEVERABILITY:

If any term of this Memorandum of Understanding is held by a Court of competent jurisdiction to be invalid or unenforceable, then this MOU including all of the remaining terms, will remain in full force and effect as if such invalid or unenforceable term had never been included.

#### J. NO IMPLIED WAIVER:

Either party's failure to insist in any one or more instances upon strict performance by the other party of any of the terms of this MOU shall not be construed as a waiver of any continuing or subsequent failure to perform or delay in performance of any term hereof.

#### K. INDEMNITY:

The parties hereto shall indemnify and hold indemnified and harmless each other, and their employees, bonafide visitors and patients from and against all allegations, claims, actions, suits, demands, damages etc. which arise out of, relate to or result from any act or omission of the parties hereto during the period of this MOU.

### L. NOTICES:

Any communication to be given in connection with this MOU shall be in writing and may be sent by duly acknowledged email, personal delivery or by registered post addressed to the parties at the addresses mentioned hereinabove: -

## 1. Dr Prashant Tembhare

Clinician Scientist and Associate Professor

Hematopathology Laboratory, TMC-ACTREC,

Sector 22, Kharghar,

Navi Mumbai 410210.

Telephone: 02227405362 Fax: 02227405148

E-mail: ptembhare@actrec.gov.in; docprt@gmail.com

Signature:

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2. Dr. Shilpi Sahu

Professor and Head

Department of Pathology, MGMMCH

Plot No. 1 & 2, Sector-1, NH-4 Junction, Mumbai- Pune Hwy,

Kamothe, Navi Mumbai, Maharashtra 410209

Telephone: +91-22 27437833

E-mail: mgmpathologyhod@gmail.com

Signature:

GARAI Medicine), DVB (General Medicine), Colic (European Diploma in Intensive Court Unit & Assistant Professor, Emergency (College & Hospital, Kamothe, Navi N

Date

## M. Independent Entities.

MGMCH and TMC-ACTREC are independent parties and neither is an agent, joint venture partners, or partner of the other.

## N. DISPUTE RESOLUTION:

In the event of any disputes or differences arising out of or in connection with this MOU whether during subsistence of this MOU or thereafter, the matter shall be referred to the Sole Arbitrator, who shall be mutually appointed by the parties, for arbitration, whose decision shall be final and binding on the parties. The proceedings before the Sole Arbitrator shall be governed by the provisions of the Arbitration and Conciliation Act 1996 and amendment thereof from time to time. The place of such arbitration should be Mumbai, conducted in English and cost of such arbitration will be equally shared by all parties.

## O. COUNTER PARTS:

This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same MOU and shall become effective when counterparts have been signed by each party and delivered to the other party.

P. GOVERNING LAW: The Parties hereto realize that the Registered Office of the TMC-ACTREC is in Mumbai and have mutually agreed that despite this MOU being executed by the other party (MGMMCH) in Navi Mumbai, for convenience and notwithstanding that part of the cause of action may arise anywhere in India, this Agreement shall be governed and construed in accordance with the laws of India under the jurisdiction of Mumbai Courts.

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IN WITNESS WHEREOF, the parties hereto have caused this Memorandum of Understanding to be executed by their duly authorized representatives as of the date first above written.

Signed, Sealed & Delivered by:	Dr. Navin Khattry
TMC-ACTREC, Mumbai	M.D.,D.M.
Through:	d Centre for Treatment Research
Dr. Navin Khattry, Deputy Director, A Navi. Navi. MUMBAI	Tata Memorial Centre, Tata Memorial Centre, The Navi Mumbal-410210, India
Dr. Sudeep Gupta,	
Director of ACTREC, TMC Dr. Sudeep Gu MBBS, MC Director.	pta , , , , , , , , , , , , , , , , , , ,
Date: 10.09.2020  Advanced Centre for Treatment River Education in Cancer (ACTR Tata Memorial Centre, Kharghar Navi Mumbai-410210	EC)
Place: Kharghar, Navi	. Ilidia
Mumbai	
Witness: Name and signature	
Signed, Sealed & Delivered by:	
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Through	Dean.
Dr. G S Narshetty, Dean MGMMCH	G.M. Medic & Hospital monte, Navi multipai - 410209
Authorized signatory	mor. c. rear man
Date: 10.09.2020	
Place: Kamothe, Navi Mumbai	
Witness:	
Name and signature	