Department of Health Research, Ministry of Health and Family Welfare, Government of India

Dated: 14 2 20

The Dean. MGM Medical College Sector- 17, Kamothe Navi Mumbai-410 209

No.5/4/1-7/2019-NCD-II

Adhoc project entitled "Randomized controlled study to assess effectiveness and acceptability of Sub: mobile app based interv3entional tool for cardiovascular disease self- management and risk factor controlled among diabetic patients' under Dr. Ipseeta Ray Mohanty, Mumbai.

Sir.

Reference the above mentioned project.

The Competent Authority of the ICMR sanctions the continuation of the above mentioned project for its remaining nine months of the 2nd year duration w.e.f. 01.12.2020 to 31.08.2021 with budget allotment of Rs.4,24,538/- (Rupees four lakhs twenty four thousand five hundred and thirty eight only) as per budget statement enclosed.

The other term and conditions will be remain the same as referred this office letter of even number dated 02.09.2019.

Yours faithfully,

(Ishwar Likhar) Administrative Officer for Director General

Copy to:

- 1. Dr. Ipseeta Ray Mohanty. Professor, Pharmacology, M.G.M Medical College, Sector- 17, Kamothe, Navi Mumbai-410 209
- 2. Accounts Section V (RFC No: NCD/Adhoc/70/2019-20 dated 30.08.2019)
- 3. IRIS Cell (ID No.2019-0502)
- 4. Administrative Officer, (NCD).

5. Mr. Hemant Kumar, Sr. Technical Officer, (NCD)

for Director General

Cefo PI. project/feat. Cefo 1650, bland

$\frac{\text{BUDGET STATEMENT FOR SIX MONTHS OF THE 2}^{\text{ND}}}{\text{FROM }01.12.2020} \xrightarrow{\text{TO }31.08.2021} \text{YEAR}$

Sub: Adhoc project entitled "Randomized controlled study to assess effectiveness and acceptability of mobile app based interv3entional tool for cardiovascular disease self- management and risk factor controlled among diabetic patients' under Dr. Ipseeta Ray Mohanty. Mumbai

Description	2 nd yr 9 months
Recurring contingency	10.7501
Contingency	18.750/-
Investigation Rs. 3000/- per patients (3 time points 0 & 3	3.00.000/-
and 6 months)	
Total patients = $300 \text{ total cost} = 300 \times 3000 = 9,00,000/-$	
Dyslipidemia	
Lipid Profile (TG, LDL, HDL, Tc) Atherogenic index (
Rs. 400/- test)	
Glycemic control	
Fasting blood sugar, Glycosylated- Rs. 100/- test	
hemoglobin Rs. 500/- test Hemostasis High- sensitivity	
C- reactive protein Rs. 500/- test Apolipoprotein A Rs.	
500 test	
Apolipoprotein A Rs. 500/- test	
Apoliporotein B1 Rs. 500/- test	27.500
Patients follow up and stationary	37,500/-
Data entry and analysis.	45,000/-
Total II	4,01,250/-
Over head charges 3%	12,038
IV. Travel	11,250/-
Grand total	4,24,538/-

(Rupees four lakhs twenty four thousand five hundred and thirty eight only)

INDIAN COUNCIL OF MEDICAL RESEARCH ANSARI NAGAR, NEW DELIH -110029.

No. 5/4/1-7/19-NCD-II

Date: 30-8-19

To

The Dean MGM Medical College, Sector-18 Kamothe, Navi Mumbai410 209

Subject: - "Randomized controlled study to assess effectiveness and acceptability of mobile app based interventional tool for cardiovascular disease self-management and risk factor control among diabetic patients" under Dr. Ipseeta Ray Mohanty, Mumbai.

Sir,

The Director-General of the Council sanctions the above mentioned research scheme initially for a period of one year from 01-09-2019 subject to extension upto the total duration specified in para 3(3) below.

The Director-General of the Council also sanctions the budget allotment of Rs. 11,26,750/-(Rupees eleven lakh twenty six thousand seven hundred fifty only) as detailed in the attached statement for the period ending the 31-08-2020.

The grant-in-aid will be given subject to the following conditions:-

- 1. The payment of the grant will be made in lump-sum to the head of the Institution. The first instalment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent instalment of the grant should be placed with the Council in the prescribed proforma attached.
 - 2. The staff appointed on the project should be paid as indicated in the budget statement attached.
 - 3. The approved duration of the scheme is 3 years. The annual extension will be given after review of the work done on the scheme during the previous year.
 - 4. A report on the progress made will be submitted to the Council as and when called for.
 - The Institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.

PTO

- The other terms and conditions are indicated in Annexure:1
- The Host Institute shall utilize the grant after following the provisions laid down in the GFRs 2017 and T. A. Rules.
- The PI may be advised to keep the fund in a separate Saving Bank Account opened for research funds received from ICMR so as to ensure that interest earned thereon is also credited in to the Fund Account.

The receipt of this letter may please be acknowledged.

(Ishwar Likhar) Admn. Officer for Director-General

Yours faithfully-

This issue with the concurrence of Finance Section vide RFC No. NCD/Adhoc/70/2019-20 dated 30/8/19

No.5/4/1-7/19-NCD-II

Copy together with a copy of the budget statement forwarded for information to Dr. Ipseeta Ray Mohanry, Professor, Pharmacology, M. G. M. Medical College, Sector-18 Kamothe, Navi 1, Mumbai-410 209.

Copy together with a copy of the budget statement forwarded to the Accounts Section for 2.

information and necessary action.

Copy together with a copy of the budget statement forwarded to the Budget Section for 3, compilation of the Council's budget.

IRIS Code Number (2019-0502) 4.

A.O., NCD. 5.

Mr. Hemnat Kumar, Sr. T. O., ICMR, New Delhi

For Director-General

Mgm Medical College Sect-18,Kamothe,Navi Mumbai

ICMR IPSEETA RAY 2019-2020 (for 3 Years) Ledger Account

1-Apr-2019 to 31-Mar-2021

						Page 1
	Davisules		Vch Type	Vch No.	Debit	Credit
Date	Particulars			572		11,26,750.00
30-9-2019	By IDBI BA	NK	Receipt	3/2		1,20,100,00
	DOM. SECO.	PRIMARY COST CATEGORY				
		Xx 11,26,750.00 Dr				
	Cheque/DD	30-9-2019 11,26,75	50.00 Dr			
	SHOWE SWILL ENGINE	Mobile App Based Intervational				
		Tool For Cardiovascular Disease				
		Self Management And Risk Control				
		Among Diabetic Patient (NEFT				
		-RBI2621926435278 - ICMR NEw				
		Delhi (Credited on 19-9-19))				
2 1 2020	To Ipseeta	Ray	Journal	555	19,669.00	
3-1-2020	10 ipscott	PRIMARY COST CATEGORY				
		O 19,669.00 Cr				
		BEING TA, REGISTRATION &				
		HOTEL CHARGES				
		REIMBURSEMENTTO DR				
		IPSEETA RAY FOR ATTENDING				
		51TH ANNUAL CONFERENCE OF				
		INDIAN PHARMACOLOGICAL				
		SOCIETY HELD AT HYDERABAD				
		FROM 5-7TH DEC-2019				
	T Innoct	a Pay	Journal	714	11,101.00	
13-3-2020	To Ipseet	PRIMARY COST CATEGORY				
		44 404 00 0-				
		0 11,101.00 Gr being ch no 951317 paid to Dr				
		Ipseeta Ray at the international				
		conference of cardiovascular				
		sciences (ICCS2020) held at delhi				
		from 21st to 23rd feb 2020(under				
		travelling exp head				
					30,770.00	11,26,750.00
					10,95,980.00	
	To Clos	ing Balance			11,26,750.00	11,26,750.00
4.4.2020	By Opening	Balance				10,95,980.00
1-4-2020	Dy Opening	g Dalanos		67	EE 000 00	
20-7-202	20 To Advan	ce to Suppliers	Journal	67	55,000.00	
		PRIMARY COST CATEGORY				
		0 55,000.00 Cr				
		being bill no 2020-21/A313 dated				
		10-06-2020 Aadi Medi solutions				
		for Body composition Analyzer				
						1000 CO. C.
		2 N 2			55,000.00	10,95,980.0
		ried Over			00,000	TO A GRADIE STORES

continued ...

Date	Particulars	Vch Type	V	ch No.		Debit	Credit
	Brought Forward					55,000.00	10,95,980.00
19-8-2020	To IDBI BANK		Payment		371	4,00,000.00	
	MEDICAL -kamothe p of funds to against lab from centra	19-8-2020 4,00,000 INO 968375 MGM COLLEGE & HOSPITAL hayment towards transfer hospital kamothe horatory investigation al diagnostic laboratory hroject. from ICMR und.	.00 Cr				
30-12-2020	By Tution Fees (RTGS) PRIMARY COST CAT Xx	EGORY 4,24,538.00 Dr	Journal		392		4,24,538.00
	being fees re	cd FROM ICMR					
23-1-2021	To Lab India PRIMARY COST CAT X	EGORY 9,025.00 Cr	Journal		510	9,025.00	
	INDIA B.P AI	NO. 014/20-21 LAB PPARATUS , ER, & STRIPS					
						4,64,025.00	15,20,518.00
To	Closing Balance					10,56,493.00	
						15,20,518.00	15,20,518.00

Mured

Dean.
M.G.M. Medical cilege & Hospital
Kamothe, Navi Mumbai - 435239





SHORT-TERM STUDENTSHIP (STS 2020)

Proposal Result

<u>IMPORTANT</u>- *The Application Attestation Form (*AAF) submitted by <u>some of the selected students</u> is incorrect/ incomplete/ signature/ stamp is missing/ not visible clearly or not filled up completely. Only those students will be sent a separate email shortly, to re-submit the correct and complete AAF to ICMR as required. The revised filled in completed AAF should be sent by email to <u>stshrd2017@gmail.com</u>by 29th June 2020 (by 3:00pm).

Please note: If required AAF is not received by 29th June, 2020 the selection of the withheld students shall stand cancelled without any further information. In case the Medical/Dental College is not yet opened due to COVID-19, then a letter from the Guide through email is required to be sent to us by 29th June 2020 stating the same, with reason.

General Information

- 1. The final list of students selected for STS 2020 Program is displayed below in order of their STS-2020 Reference ID. There will be no second list.
 - Please note: Always quote your STS Reference ID for any future correspondence emails to ICMR.
 - DO NOT SEND EMAILS ASKING FOR REASONS OF REJECTION/COMMENTS etc. Such emails will not be entertained or corresponded. (Pl. see STS Guidelines for details).
- 2. Each application was reviewed independently by group of Experts for its scientific value and selections have been made as per scores obtained.
- 3. In wake of the current <u>COVID-19 health emergency</u> majority of Medical/Dental Colleges/Hospitals/Institutes are closed, <u>therefore the Report submission for STS 2020 will be further decided only once the Govt. of India and various State Govt. decide to re-open all the Medical/Dental Colleges/Institutions.</u>
- 4. So you may wait until the decision is declared by Govt. of India and various State Govt. and then proceed to carry out the proposed research work for STS 2020, and accordingly ICMR will then upload the revised schedule for STS 2020 Report submission guidelines and timelines.
- 5. The research carried out by the student must be in compliance with ICMR "Ethical Guidelines for Biomedical Research on Human Participants, 2017" which may be downloaded from ICMR website

C4.5	0000 04505	Ma Libritha C	
615 616	2020-04525 2020-04526	Ms. Likhitha S Ms. Reshma Rajeev	Approved
617	2020-04527	Ms. Shallin Reema S.	Approved
	2020-04527		Approved
618		Ms. Anahy Tarus Agraval	Approved
619	2020-04577	Ms. Anshu Tarun Agrawal	Approved
620	2020-04578	Mr. Anil R Rathod	Approved
621	2020-04582	Ms. Alenta Merin Babu	Approved
622	2020-04585	Mr. Thomas J Mannath	Approved
623	2020-04586	Ms. Sheryl Ann Antony	Approved
624	2020-04587	Mr. Parth Kalpesh Patel	Approved
625	2020-04593	Ms. Jaiversni Rajendran	Approved
626	2020-04598	Ms. Abhilasha Singh	Approved
627	2020-04599	Ms. Shreeya Vaibhav Pradhan	Approved
628	2020-04600	Ms. Sana Shabbir Khan	Approved
629	2020-04601	Ms. V Pooja	Approved
630	2020-04605	Mr. Rahul Rai	Approved
631	2020-04612	Ms. Medhavini Shivanand Angadi	Approved
632	2020-04617	Ms. Sri Vasavi Yarram	Approved
633	2020-04638	Mr. Abhishek Kumar	Approved
634	2020-04642	Ms. Bushra Sulmaz	Approved
635	2020-04644	Ms. Chavali Sai Chandralekha	Approved
636	2020-04659	Mr. Krishna Vishwanatha Kini	Approved
637	2020-04665	Ms. Pragya Gupta	Approved
638	2020-04666	Mr. Abhijeet Raju Chaudhary	Approved
639	2020-04668	Mr. Sunag Padukudru	Approved
640	2020-04670	Ms. Krishna Priya T	Approved
641	2020-04672	Mr. Shyam Chaitanya	Approved
642	2020-04675	Ms. Saurvee Bedarker	Approved
643	2020-04681	Ms. Shriya Ravichandran	Approved
644	2020-04682	Ms. Smriti Venkatesh	Approved
645	2020-04688	Ms. Lakshika Sharma	Approved
646	2020-04705	Ms. Tanisha Thomas	Approved
647	2020-04715	Ms. Roshini	Approved
648	2020-04732	Ms. Sree Laya Kalluru	Approved
649	2020-04741	Ms. Mantha Mani Kruthika	Approved
650	2020-04749	Ms. Deepshidha Velpandian	Approved
651	2020-04754	Ms. Christina Treville Pereira	Approved
652	2020-04755	Mr. Shayon Mukherji	Approved
653	2020-04761	Ms. Deepanshi	Approved
654	2020-04763	Ms. Tuba Fathima	Approved
655	2020-04767	Mr. Girik Rajesh Rohira	Approved
656	2020-04769	Mr. Raghav Prasad	Approved
657	2020-04770	Mr. Shreyas Mukeshkumar Virvani	Approved
658	2020-04774	Ms. Bhagyashree Atul Tayade	Approved
			, ,pp10704



भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research

Department of Health Research, Ministry of Health
and Family Welfare, Government of India

File No 5/10/FR/40/2020-RBMCH

Dated: 12-08-2021

The Vice Chancellor, MGM Institute of Health Sciences Navi Mumbai - 410209

Subject:- Sanction of budget allotment for the Ad-hoc research proposal entitled "Impact of Radiations from Cell Phone Towers and Cell Phone Use on Health and Development (including Neurodevelopmental Changes) of children: A Multidisciplinary Collaborative Cohort Study" under Dr. Maninder Singh Setia.

Sir/Madam,

The Director General, ICMR has been sanctioned the above-mentioned research proposal for the total period of 3 years with budget of Rs. 1,05,80,203/- (Rupees One Crore Five Lakh Eighty Thousand Two Hundred Three Only) (copy enclosed). This proposal has been sanctioned initially for three year from 20.08.2021 to 19.08.2024 and it may be extended on the yearly basis after review of the work done during the period. The grant-in-aid will be given subject to the following condition.

- The payment of the grant will be made in lump-sum to the Head of the Institute. The first installment of the grant will be paid generally as soon as report regarding appointment of the staff is received by the Council. The Staff appointed on the project should be paid as indicated in the budget statement.
- The staff on the project will be recruited as per the rules and procedure of the host institute and second part of the undertaking be obtained from the employees of the project. The staff grant will not be released unless the required undertaking [part-II] from Head of the Institute is received in this office.
- 3. The demand for payment of the subsequent installment of the grant should be placed with the Council in the prescribed Performa.
- 4. Five copies of the annual progress report should be submitted to the ICMR every year after completion of ten months of the project giving complete actual details of the research work done. Failure to submit the report in time may lead to termination of project.
- 5. Subject to the condition that the grant will be utilize after following the provisions laid down in the GFRs-2017 & TA Rules.
- Please keep the fund in the separate saving Bank Account opened for ICMR funded Research projects so that interest earned thereon
 is credited into the accounts.
- 7. The receipt of this letter may please be acknowledged.

Yours faithfully,

(Ramesh Kumar) Administrative Officer For Director General

Copy together with a copy of the budget statement forwarded to information to

- 1. Dr. Maninder Singh Setia, Epidemiologist, Mahatma Gandhi Mission Institute of Health Sciences, Mumbai.
- 2. Accounts. V. for information.
- 3. IRIS Cell No. 2020-0335
- 4. Sr. B.S. Yadav "Sr. TO" RBMCH

Director neces

23/8/21

5/10/FR/40/2020-RBMCH

E-office - 111397

Date of Start: 15.08.2021

Duration: 3 years

IRIS Cell No. 2020-0335

RFC No. RBMCH/Adhoc/12/2021-22 dated: 29/07/2021

Project entitled "Impact of Radiations from Cell Phone Towers and Cell Phone Use on Health and Development (including Neurodevelopmental Changes) of children: A Multidisciplinary Collaborative Cohort Study" under Dr. Maninder Singh Setia.

Budget for 1st year 20-08-2021 to 19-08-2022

Particular	1 st year
Man Power	
Scientist C = 01 (Non-Medical) Rs. 51,000 + 6660	6,91,920
(30% HRA) = 57,660 x 12 = 6,91,920	
Laboratory Technician = 01 Rs. 18000 x 12 =	2,16,000
2,16,000	
Data Entry Operator = 1 Rs. $17,000 \times 12 = 2,04,000$	2,04,000
Field Worker 02 Rs. $18,000 \times 12*2 = 4,32,000$	4,32,000
Non-Recurring	2,50,000
Calibration of the Spectrum analyzer	
Questionnaire	2,00,000
Dosimeters	1,50,000
Contingency	12,00,000
AMC Charges	1,00,000
Travel	1,00,000
Other Travel	25,000
Overhead 3% (except travel and Equipments)	85,318
Grant Total	Rs. 36,54,238

Total Budget allotment of Rs. 36,54,238/- (Rupees Thirty Six Lakh Fifty Four Thousand Two Hundred Thirty Eight Only)

Administrative Officer For Director General



भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research

Department of Health Research, Ministry of Health
and Family Welfare, Government of India

F. No. 5/10/FR /40/2020-RBMCH Date: 12.08.2021

Subject:- Payment of 1st & final installment of the 1st year grant-in-aid for the project entitled" "Impact of Radiations from Cell Phone Towers and Cell Phone Use on Health and Development (including Neurodevelopment Changes) of children: A Multidisciplinary Collaborative Cohort Study" under Dr. Maninder Singh Setia.

MAMORANDUM

The Director General of the ICMR sanctions the grant of Rs. 36,54,238/- (Rupees Thirty Six Lakh Fifty Four Thousand Two Hundred Thirty Eight Only) as the 1st installment of the 1st year grant for the period from 20.08.2021 to 19.08.2022 for incurring expenditure in connection with the above mentioned project.

The amount of Rs. 36,54,238/- may be debited to the provision made of Rs. 36,54,238/- on the above mentioned research project for the year 2021-2022.

A formal bill for Rs. 36,54,238/- is sent herewith for payment release by NEFT/RTGS in favour of The Vice Chancellor, MGM Institute of Health Sciences, Navi Mumbai - 410209. This issued with the concurrence of the Finance Divn., vide RFC No. RBMCH/Adhoc/12/2021-22 dated: 29/07/2021.

(Ramesh Kumar)
Administrative Officer
For Director General

Accounts. V. ICMR

- 1. Copy to: **The Vice Chancellor,** MGM Institute of Health Sciences, Navi Mumbai 410209. The grant has been sanctioned on the conditions laid down in out letter referred to above.
- 2. **Dr. Maninder Singh Setia**, Epidemiologist, Mahatma Gandhi Mission Institute of Health Sciences, Mumbai. It is requested that an audited statement of account together with utilization certificate of the grant received and utilized in last year grant may kindly be sent to this office.
- 3. IRIS Cell No. 2020-0335
- 4. Sr. B.S. Yadav "Sr. TO" RBMCH



Letter of Intent

5th July, 2021

To

Dr. Pallavi Palaskar and the Team

Sub: LOI to partner with AIC-AMTZ Medi-Valley Incubation Council.

Dear Innovator,

At the onset, Congratulations! It is a pleasure to inform you that subsequent to your participation in the selection rounds, your innovation has been shortlisted at the AIC-AMTZ Medi-Valley Incubation Council.

Medi Valley is a MedTech dedicated incubation centre in the country, set up at Andhra Pradesh MedTech Zone (AMTZ), which is the pioneering and till date only medical devices ecosystem comprising of manufacturing, innovation, scientific facilities, regulatory, standards, IP and all other allied facilities under one geographical entity.

This letter of Intent (LOI) is an offer to you for availing the facilities at the AMTZ ecosystem for the development, build and validation of prototypes of your innovation. The incubation support would entail:

- I. Incubation centre laboratory access.
- II. Industrial Scientific Facilities at AMTZ for testing and validation (3D Printing facility, Biomaterial testing, Pre-Clinical large animal studies, EMI/EMC, Gamma irradiation, X-Ray and CT Scan manufacturing and Validation and the like.
- III. Upto 10 Lakhs per product developed as on-boarding incentive for components, supplies and other scientific costs covering cost of 5 prototypes.
- IV. Access to readily available moulds.
- V. Access to state-of-the-art sensors and PCBs.
- VI. Access to validation and testing facilities.
- VII. Access to dedicated production machinery.
- VIII. Market Access avenues for the end products after successful product realization.

Please confirm your willingness to accept this offer by signing the LOI below.

This LOI does not confer any right on the addressee for any legal commitment by the management of Medi Valley and the confirmation shall have to be legally taken forward by signing an agreement with AIC – AMTZ Medi-Valley Incubation Council.

With Regards,

For AIC - AMTZ Medi-Valley Incubation Council

(Dr Anand Krishnan)

Chief Executive Officer

ceo@medivalley-aic.in

For Dr. Pallavi Palaskar and the Team

(Authorized Signature)



महाराष्ट्र MAHARASHTRA

O 2019 O

AU 730498



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

Ramothe, Navanne (val - 410209

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 वर्णनं महाक विकत पंजा यह विकास वाली इस या पशकारिय नाव... मिर्वे कार कार कार पाडे रेटेव वंडर, फटवाली पन्दाना मुद्देश विक्रेन्य भी तुकान नं. ती १, सेक्टर ३ई/ए, करवाती. जि. सवगड सही पादाना अक्षाक वसंच मुटार विकास दिलाम ह 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.

Dean.
MG.M Medic: 8 Hospital
Kamothe, Navimumbar-410209

Page 2 of 8

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:

firm A Punning

* Hospital

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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:	ed Centre for Treatment Research
Dr. Navin Khattry, Deputy Director, A Williams Reviews Market Mumbai	Tata Memorial Centre, Tata Memorial Centre, Nevi Mumbal-410210. India
Dr. Sudeep Gupta,	
Director of ACTREC, TMC Dr. Sudeep Gu MBBS, M Director,	upta ND, DM
Date: 10.09.2020 Advanced Centre for Treatment I Education in Cancer (ACT Tata Memorial Centre Kharghar Navi Mumbai-4102	REC)
Place: Kharghar, Navi	o. India
Mumbai	
Witness: Name and signature	
Signed, Sealed & Delivered by:	
MGMMCH	06
Through	Dean.
Dr. G S Narshetty, Dean MGMMCH	G.M. Medics 8. Hospital amortic, Navi mathuai - 410209
Authorized signatory	
Date: 10.09.2020	
Place: Kamothe, Navi Mumbai	
Witness:	
Name and signature	



Updates on ICMR COVID-19 project

2 messages

Prashant Tembhare <docprt@gmail.com>

Thu, Feb 24, 2022 at 6:45 PM

To: mgmpathologyhod@gmail.com, drshilpisahu1974@gmail.com, drsagarsinha@gmail.com

Dear Dr. Shilpi and Dr Sagar,

Hope you are doing well.

I would like to give you the update of our COVID19 project.

We have enrolled 42 patients from MGM. Patients with only one or no follow-up have been excluded from the study. The following table shows the details.

Group 1	Group	Total eurolled	ouly 1 time point	only 2 or more time point	complete Follow-up	Final enrollment total
	Asymptomatic	7	6		-	
Group 2	Symptomatic (Mild Moderate)	16	36			3
Group 3	Symptomatic (Severe)		16		2	2
Group 4	Symptomatic (Severe Sequelae-ARDS Sepsis Septic shock)	15		12	4	12
	- ARDS Sepsis Septic shock)	25		Server Research	0	25
	Total	63				

Currently, we have gathered all flow cytometric data in NNF Bangalore centre (NNF) and it is being analyzed for statistical analysis.

Also, additional serum-based tests are done at NNF.

We are hoping to finish the study in May or June.

I will keep you updated with the progress of the final results of our study.

I really appreciate and thank the MGM team, especially Dr. Sagar and Dr. Shilpi for their active participation and

my best regards

Prashant Tembhare, MD

Clinician Scientist & Professor Hematopathology Laboratory Tata Memorial Centre Mumbai

Shilpi Sahu <drshilpisahu1974@gmail.com> To: Prashant Tembhare <docprt@gmail.com>

Thank you Dr. Prashant for the update. [Quoted text hidden]

Fri, Feb 25, 2022 at 7:32 AM