Government of India
Ministry of Human Resource Development

MHRD'S
INNOVATION CELL
(GOVERNMENT OF INDIA)

INSTITUTION'S
INNOVATION
COUNCIL
(Ministry of HRD Initiative)

AICTE

CERTIFICATE

Institution Innovation Council (IIC) established at

MGM Institute of Health Sciences, Navi Mumbai, Navi Mumbai

had undertaken various activities prescribed by Innovation Cell, Ministry of HRD, Govt. of India to promote Innovation and Start-up in campus during the IIC calendar year 2018-19.

Prof.Anil D.Sahasrabudhe
Chairman, AICTE

Shri. R. Subrahmanyam
Secretary, MHRD

Abhay Jere

Dr. Abhay Jere
CIO, MHRD, Innovation Cell

National Accreditation Board for Hospitals & Healthcare Providers

(Constituent Board of Quality Council of India)

Certificate of Accreditation

MGM Medical College Hospital and Medical Center Research Institute (MCRI)
Central Naka Road, N-6, CIDCO
Aurangabad - 431003, Maharashtra

has been assessed and found to comply with NABH Accreditation Standards for Hospitals. This certificate is valid for the Scope as specified in the annexure subject to continued compliance with the accreditation requirements.

Valid from : September 16, 2018
Valid thru : September 15, 2021

PATIENT SAFETY & QUALITY OF CARE
NABH
★ ACCREDITED ★

Certificate No.
H-2018-0573

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Dr. Harish Nadkarni
Chief Executive Officer

National Accreditation Board for Hospitals & Healthcare Providers, 5th Floor, ITPI Building, 4A, Ring Road, IP Estate, New Delhi 110 002, India
Phone: +91-11-42600600, Fax: +91-11-2332 3415 • Email: helpdesk@nabh.co • Website: www.nabh.co

ISQua Accreditation ORGANISATION
ISQua Accreditation STANDARDS

NABH and the NABH Accreditation Standards for Hospitals are ISQua Accredited

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

CERTIFICATE OF ACCREDITATION

MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number: MC-2166

Issue Date: 26/04/2019 **Valid Until:** 25/04/2021

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Signed for and on behalf of NABL

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

N. Venkateswaran
Chief Executive Officer (I/c)

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	1 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
Permanent Facility						
1	CLINICAL BIOCHEMISTRY	Serum	Bilirubin -Indirect	Calculation	NA	NA
2	CLINICAL BIOCHEMISTRY	Serum	Calcium	Arsenoazo III	2 to 12 mg/dl	2.5
3	CLINICAL BIOCHEMISTRY	Serum	Cholesterol- LDL	Calculation	NA	NA
4	CLINICAL BIOCHEMISTRY	Serum	Cholesterol- Total	CHOD.POD (Enzyme colour test)	56 to 350 mg/dl	3.3
5	CLINICAL BIOCHEMISTRY	Serum	Ferritin	Electrochemiluminescence	2.0 to 1500 ng/ml	6.2
6	CLINICAL BIOCHEMISTRY	Serum	Globulin	Calculation	NA	NA
7	CLINICAL BIOCHEMISTRY	Serum	LDH	Lactate to pyruvate; IFCC 370	4 to 4750 U/L	6.6
8	CLINICAL BIOCHEMISTRY	Serum	PSA	Electrochemiluminescence	0.5 to 150 ng/ml	6.1
9	CLINICAL BIOCHEMISTRY	Serum	VLDL cholesterol	Calculation method	NA	NA
10	CLINICAL BIOCHEMISTRY	Urine	Calcium	Arsenoazo III	0.0 to 40.0 mg/dl	5

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	2 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
11	CLINICAL BIOCHEMISTRY	Urine	Creatinine	Modified Jaffe's (Kinetic method)	1.0 to 300 mg/dl	3.0
12	CLINICAL BIOCHEMISTRY	Urine	Microalbumin	Immunoturbidometric	0.5 to 300 mg/dl	3.0
13	CLINICAL BIOCHEMISTRY	Urine	Phosphorus	Molybdate UV	10.0 to 200 mg/dl	3.0
14	CLINICAL BIOCHEMISTRY	Urine	Urea	Urease GLDH Kinetic	20 to 1300 mg/dl	5.0
15	CLINICAL BIOCHEMISTRY	Urine	Uric Acid	Uricase POD(Enzyme colour test	1.0 to 100 mg/dl	3.0
16	CLINICAL BIOCHEMISTRY	Serum	Albumin	BCG	0.6 to 4.0 g/dl	2.5
17	CLINICAL BIOCHEMISTRY	Serum	Alkaline Phosphatase	IFCC (Kinetic Colour test with AMP buffer)	15 to 650 U/L	7.7
18	CLINICAL BIOCHEMISTRY	Serum	ALT/SGPT	IFCC without Pyridoxal phosphate (Kinetic UV test)	07 to 6100 U/L	6.1
19	CLINICAL BIOCHEMISTRY	Serum	Amylase	pNPG7(kinetic Colour test)	10 to 2365 U/L	3.7
20	CLINICAL BIOCHEMISTRY	Serum	AST/SGOT	IFCC without Pyridoxal phosphate (Kinetic UV test)	6 to 8419 U/L	3.7

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	3 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
21	CLINICAL BIOCHEMISTRY	Serum	Bilirubin -Direct	DPD Colour test	0.01 to 39 mg/dl	5.4
22	CLINICAL BIOCHEMISTRY	Serum	Bilirubin -Total	DPD Colour test	0.01 to 60 mg/dl	3.0
23	CLINICAL BIOCHEMISTRY	Serum	Cholesterol- HDL	CHOD.POD (Enzyme colour test, Immuno-Inhibition)	13 to 90 mg/dl	5.3
24	CLINICAL BIOCHEMISTRY	Serum	CPK-NAC	IFCC (Kinetic Colour test)	20 to 3000 U/L	5.1
25	CLINICAL BIOCHEMISTRY	Serum	Creatinine	Modified Jaffe' /Kinetic Method (Kinetic colour test)	0.1 to 14 mg/dl	4.5
26	CLINICAL BIOCHEMISTRY	Serum	FSH	Electrochemiluminiscence	0.100 to 200 mIU/ml	6.2
27	CLINICAL BIOCHEMISTRY	Serum	FT3	Electrochemiluminiscence	0.26 to 21 pg/ml	8.4
28	CLINICAL BIOCHEMISTRY	Serum	FT4	Electrochemiluminiscence	0.023 to 7.76 ng/dl	10.5
29	CLINICAL BIOCHEMISTRY	Serum	Iron	Colorimetric without PPT	10 to 1000 micrograms/dl	4.5
30	CLINICAL BIOCHEMISTRY	Serum	LH	Electrochemiluminiscence	0.100 to 200 mIU/ml	8.2

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	4 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
31	CLINICAL BIOCHEMISTRY	Serum	Phosphorus	Molybdate UV	1.4 to 16.5 mg/dl	5.0
32	CLINICAL BIOCHEMISTRY	Serum	Potassium	ISE by Indirect Method	1.6 to 9.0 meq/L	3.2
33	CLINICAL BIOCHEMISTRY	Serum	Prolactin	Electrochemiluminiscence	1.0 to 10000 microIU/ml	10.8
34	CLINICAL BIOCHEMISTRY	Serum	Sodium	ISE by Indirect Method	48 to 167 meq/L	2.5
35	CLINICAL BIOCHEMISTRY	Serum	T3	Electrochemiluminiscence	0.195 to 6.5 ng/ml	7.1
36	CLINICAL BIOCHEMISTRY	Serum	T4	Electrochemiluminiscence	0.42 to 24.86 micrograms/dl	10.0
37	CLINICAL BIOCHEMISTRY	Serum	Total Protein	Biuret End PT	2.0 to 10 g/dl	4.4
38	CLINICAL BIOCHEMISTRY	Serum	Triglycerides	GPO PAP (Enzyme colour test)	37 to 900 mg/dl	4.5
39	CLINICAL BIOCHEMISTRY	Serum	TSH	Electrochemiluminiscence	0.005 to 100 microIU/L	4.6
40	CLINICAL BIOCHEMISTRY	Serum	UIBC	Fe-UIBC (saturation with Iron)	55 to 450 micrograms/dl	7.0

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	5 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
41	CLINICAL BIOCHEMISTRY	Serum	Urea	Urease, GLDH kinetic	9 to 2000 mg/dl	3.2
42	CLINICAL BIOCHEMISTRY	Serum	Uric acid	Uricase,POD (Enzyme colour tests)	1.5 to 37 mg/dl	3.3
43	CLINICAL BIOCHEMISTRY	Serum	Vitamin B12	Electrochemiluminiscence	30 to 2000 pg/ml	8.1
44	CLINICAL BIOCHEMISTRY	Serum	Vitamin D	Electrochemiluminiscence	0 to 70 ng/ml	12.3
45	CLINICAL BIOCHEMISTRY	Serum/Plasma	Glucose	Hexokinase	40 to 800 mg/dl	4.3
46	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Plasma	APTT	Clotting assay by optical nephlometry	20 to 120 Seconds	4.8
47	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Plasma	Prothrombin Time	Clotting assay by optical nephlometry	8 to 120 Seconds	4.9
48	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Differential count-Basophils	Electrical impedance laser lightscattering and dye bonding	0 to 100 %	16.3

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	6 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
49	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Differential count- Eosinophils	Electrical impedance laser lightscattering and dye bonding	0 to 100 %	18.9
50	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Differential count- Lymphocytes	Electrical impedance laser lightscattering and dye bonding	0 to 100 %	8.5
51	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Differential count- Monocytes	Electrical impedance laser lightscattering and dye bonding	0 to 100 %	14.7
52	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Differential count- Neutrophils	Electrical impedance laser lightscattering and dye bonding	0 to 100 %	4.6
53	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Heamoglobin	Electrical impedance laser lightscattering and dye bonding	0 to 22.5 g/dl	1.5
54	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Hematocrit	Calculated from the RBC count & MCV	NA	2.1

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	7 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
55	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Mean Corpuscular Haem. Concent. (MCHC)	Mathematical calculation	NA	2.1
56	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Platelets	Electrical impedance laser lightscattering and dye bonding	0.05 to 10.0 lakhs/cumm	13.6
57	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	RBC	Electrical impedance laser lightscattering and dye bonding	0 to 99.99 $x10^6$/µL	2.5
58	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Total Leucocyte Count (TLC)	Electrical impedance laser lightscattering and dye bonding	0.02 to 999.999 $x10^3$/µL	4.4
59	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Erythrocytes Sedimentation Rate	Westergren's Method	1.0 to 150 mm/hour	NA
60	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Malaria Antigen	Ag-Ab Immunoassay [HRP 2 for p. Falciparum and PAN specific for pLDH for Plasmodiun species (P. Falciparum, P. Vivax, P. malariae, P. Ovale)]	NA	NA

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	8 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
61	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Malarial Parasites	Staining of Thick & Thin Smear	NA	NA
62	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Mean Corpusc. Volume (MCV)	Low angle light scatter	NA	1.0
63	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Mean Corpuscular Haemoglonin (MCH)	Mathematical calculation	NA	1.7
64	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Peripheral Smear	Microscopy by Leishman/ Field's stain	NA	NA
65	HAEMATOLOGY & IMMUNOHAEMATOLOGY	Whole blood	Reticulocytes Count	Supravital Staining	NA	NA
66	HISTOPATHOLOGY	Tissue biopsy & Large specimen	H & E (Hematoxylin and eosin)	Tissue processing by semiauto histokinette and cuttting by leica microtome	Qualitative(NA)	NA
67	MICROBIOLOGY & SEROLOGY	Serum	CRP	Slide agglutination	Qualitative	NA

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	9 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
68	MICROBIOLOGY & SEROLOGY	Serum	Dengue IgG, IgM	Immunochromatography	Qualitative	NA
69	MICROBIOLOGY & SEROLOGY	Serum	Dengue NS1	Immunochromatography	Qualitative	NA
70	MICROBIOLOGY & SEROLOGY	Serum	HBsAg	Immunochromatography	Qualitative	NA
71	MICROBIOLOGY & SEROLOGY	Serum	RA	Slide agglutination	Qualitative	NA
72	MICROBIOLOGY & SEROLOGY	Serum	RPR	Slide Flocculation	Qualitative	NA
73	MICROBIOLOGY & SEROLOGY	Sputum, urine, body fluids, pus, stool, CSF, ET secretions, suction tip, central venous catheter tip, Foley's tip, Jelco tip, tissue/ biopsy, swabs, clot, eye, ear, urethral, cervical, semen, OT swabs, exposed plates, gastric aspirates, conjunctival, corneal, umbilical, Bal.	Aerobic Culture & Sensitivity	Conventional & Kirby Bauer's Disc Diffusion Method	Qualitative	NA

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	10 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
74	MICROBIOLOGY & SEROLOGY	Blood	Aerobic culture & Sensitivity	Conventional & Kirby Bauer's Disc Diffusion method	Qualitative	NA
75	MICROBIOLOGY & SEROLOGY	Blood	BactAlert Blood Culture	Automated Blood culture system	Qualitative	NA
76	MICROBIOLOGY & SEROLOGY	Serum	ASO	Slide Agglutination	Qualitative	NA
77	MICROBIOLOGY & SEROLOGY	Serum	HCV TRI-DOT	Dot Immunoassay	Qualitative	NA
78	MICROBIOLOGY & SEROLOGY	Serum	HIV 1 and 2 Meriscreen	Lateral flow Immunochromatography	Qualitative	NA
79	MICROBIOLOGY & SEROLOGY	Serum	HIV COMBAIDS	Dot Immunoassay	Qualitative	NA
80	MICROBIOLOGY & SEROLOGY	Serum	Signal HIV	Immunodot assay	Qualitative	NA
81	MICROBIOLOGY & SEROLOGY	Serum	WIDAL	Slide & Tube agglutination	Qualitative	NA

SCOPE OF ACCREDITATION

Laboratory Name	MGM MEDICAL COLLEGE HOSPITALS, CENTRAL LABORATORY, PLOT NO 1 AND 2, NH4 JUNCTION, SION PANVEL EXPRESS WAY, MUMBAI, MAHARASHTRA, INDIA		
Accreditation Standard	ISO 15189:2012		
Certificate Number	MC-2166	Page No. :	11 / 11
Validity	26/04/2019 to 25/04/2021	Last Amended on	-

S.No	Discipline	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing/ Limits of Detection	%CV
82	MICROBIOLOGY & SEROLOGY	Sputum, Extrapulmonary Samples	GeneXpert for Mycobacterium tuberculosis	Real time PCR	Qualitative	NA
83	MICROBIOLOGY & SEROLOGY	Sputum, Urine, Body Fluids, Pus, CSF.	Gram stain	Microscopy	Qualitative	NA
84	MICROBIOLOGY & SEROLOGY	Sputum, Urine, Body Fluids, Pus, CSF.	Ziehl Neelsen stain	Microscopy	Qualitative	NA
85	MICROBIOLOGY & SEROLOGY	Stool	Detection of Intestinal cyst, ova, trophozoites and larvae	Microscopy	Qualitative	NA

UNESCO
הקתדרה לביו־אתיקה של אונסקו
UNESCO Chair in Bioethics
המרכז הבינלאומי לבריאות, משפט ואתיקה, הפקולטה למשפטים, אוניברסיטת חיפה
The International Center for Health, Law and Ethics, University of Haifa
ראש הקתדרה: פרופ' אמנון כרמי
Chairholder: Prof. Amnon Carmi

10th August 2016

Dr Sudhir N Kadam
Vice Chancellor
MGM Institute of Health Sciences

Professor Russell Dsouza
Head Asia Pacific Program
Melborne Australia

Esteemed Colleagues,

On establishing requirement of the UNESCO Chair in Bioethics (Haifa) having been met, I hereby issue this writ confirming and approving the establishment of the Bioethics Unit of the Indian Program of the UNESCO Chair and of the International Bioethics Network of the UNISCO Chair in Bioethics at:

The MGM Institute of Health Sciences
Sector 1, Kamothe,
Navi Mumbai – 410 209
INDIA

Amnon Carmi

Prof. Amnon Carmi,
Head & Chair Holder
UNESCO Chair in Bioethics

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

MGM'S CENTRAL PATHOLOGY LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

Mahatma Gandhi Mission Hospital, N-6, CIDCO, Aurangabad, Maharashtra

in the field of

MEDICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number M-0692

Issue Date 03/06/2016

Valid Until 02/06/2018

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

Dr. Vandana Jain	Anil Relia	Prof. S.K. Joshi
Program Manager	Director	Chairman

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

CERTIFICATE OF ACCREDITATION

MGM'S CENTRAL PATHOLOGY LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

Mahatma Gandhi Mission Hospital, N-6, CIDCO, Aurangabad, Maharashtra

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

in the field of

MEDICAL TESTING

Certificate Number	MC-2839		
Issue Date	29/06/2018	**Valid Until**	28/06/2020

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Signed for and on behalf of NABL

8907697030001000051 1

Anil Relia
Chief Executive Officer

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

SCOPE OF ACCREDITATION

Laboratory MGM's Central Pathology Laboratory, Mahatma Gandhi Mission Hospital, N-6, CIDCO, Aurangabad, Maharashtra

Accreditation Standard ISO 15189: 2012

Certificate Number MC-2839 **Page 1 of 3**

Validity 29.06.2018 to 28.06.2020 **Last Amended on** --

Sl.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
			CLINICAL BIOCHEMISTRY		
1.	Serum/Plasma	Albumin	Bromocresil Green (BCG)	1.00 – 6.00 g/dl	2.9
2.	Serum/Plasma	Alkaline Phosphatase	PNPP, AMP Buffer-Vitros	20.00 -1500 U/L	4.3
3.	Serum/Plasma	ALT	UV with P5P - Vitros	6.00 – 100.0 U/L	8.6
4.	Serum/Plasma	Amylase	Amylopectin, Colorimetric - Vitros	30 – 1200 U/L	8.0
5.	Serum/Plasma	AST	Enzymatic, Colorimetric	3.00 - 750 U/L	4.1
6.	Serum/Plasma	Bilirurbin Total	Dual Wavelength-Vitros	0.10 - 27.00 mg/dl	7.3
7.	Serum/Plasma	Bilirurbin Direct	Calculated	0.10 - 27.00 mg/dl	NA
8.	Serum/Plasma	Cholesterol HDL	Direct Measure, PTA/Mgcl2-Vitros	5.00 – 110.00 mg/dl	4.1
9.	Serum/Plasma	Cholesterol Total	Cholestrol Oxidase, Esterase, Peroxidase	50.00 – 325.00 mg/dl	2.1
10.	Serum/Plasma	Creatinine	Enzymatic-Vitros IFCC	0.05 – 14.00 mg/dl	1.9
11.	Serum/Plasma	LDL Cholesterol	Calculated	NA	NA
12.	Serum/Plasma	VLDL Cholesterol	Calculated	NA	NA
13.	Serum/Plasma	Total To HDL Cholesterol Ratio	Calculated	NA	NA
14.	Serum/Plasma	Globulin	Calculated	NA	NA
15.	Plasma	Glucose	Glucose Oxidase, H2O2 (TRinder)	20.00 – 625.00 mg/dl	5.2
16.	Serum/Plasma	Bilirurbin Indirect	Dual Wavelength-Vitros	0.01 - 27.00 mg/dl	7.9
17.	Serum/Plasma	Calcium	Arsenazo III-Vitros	1.00 – 14.00 mg/dl	1.8
18.	Serum/Plasma	Lipase	Enzymatic with Colipase	10.00 – 2000 U/L	6.7
19.	Serum/Plasma	Phosphorus	Phosphomolybdate Reduction	0.50 – 13.00 mg/dl	3.2
20.	Serum/Plasma	Protein Total	Biurest Endpoint	2.00 – 11.00 g/dl	2.6
21.	Serum/Plasma	Urea/ Bun	Urease Colorimetric	2.00 – 120.00 mg/dl	3.7
22.	Serum/Plasma	Triglycerides	Enzymatic Endpoint	10.00 – 525 mg/dl	1.9
23.	Serum/Plasma	Uric Acid	Uricase Colorimetr	0.5 – 17.00 mg/dl	3.1
24.	Serum/Plasma	Creatine Kinase(CK)	Rosalki, Other Modified VIT	20.00 – 1600 U/L	3.7
25.	Serum/Plasma	LDH	L to P IFCC ref.Proc.Cal	100 – 2150 U/L	4.2

Syed Tahira Rizvi
Convenor

Ritu Kulshrestha
Program Manager

National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)

SCOPE OF ACCREDITATION

Laboratory MGM's Central Pathology Laboratory, Mahatma Gandhi Mission Hospital, N-6, CIDCO, Aurangabad, Maharashtra

Accreditation Standard ISO 15189: 2012

Certificate Number MC-2839

Validity 29.06.2018 to 28.06.2020 **Last Amended on** --

Sl.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
26.	Serum/Plasma	Sodium	ISE	20 – 250 mmol/L	1.9
27.	Serum/Plasma	Potassium	ISE	0.2 – 20 mmol/L	3.0
28.	Serum/Plasma	T3	CLIA	0.103 – 12.00 ng/ml	14.9
29.	Serum/Plasma	T4	CLIA	0.405 – 24.9 ug/dl	14.7
30.	Serum/Plasma	TSH	CLIA	0.015 – 100 mIU/L	19.0
31.	Serum/Plasma	FT3	CLIA	0.50 – 22.8 pg/mL	18.7
32.	Serum/Plasma	FT4	CLIA	0.07 – 6.99 ng/dL	25.4
33.	Serum/Plasma	Ferritin	CLIA	0.299 – 1000 ng/mL	12.0
34.	Serum/Plasma	Vitamin B12	CLIA	159 – 1000 pg/mL	13.6
35.	Serum/Plasma	Folic Acid (Folate)	CLIA	0.34 – 20.0 ng/mL	23.9
36.	Serum/Plasma	Vitamin D3	CLIA	8.0 – 150 ng/mL	28.2
37.	Serum/Plasma	CEA	CLIA	0.31 – 400 ng/mL	11.9
38.	Serum/Plasma	CA - 125	CLIA	5.5 – 1000 U/mL	30.1
39.	Serum/Plasma	CA – 19.9	CLIA	1.4 – 1000 U/mL	12.6
40.	Serum/Plasma	AFP	CLIA	0.476 – 500 IU/mL	14.3
41.	Serum/Plasma	Total PSA	CLIA	0.010 – 100 ng/mL	17.9
42.	Serum/Plasma	Beta HCG	CLIA	2.39–15,000 mIU/mL	27.5
43.	Serum/Plasma	FSH	CLIA	0.66 – 200 mIU/ml	20.2
44.	Serum/Plasma	LH	CLIA	0.216 – 200 mIU/ml	14.7
45.	Serum/Plasma	Prolactin	CLIA	30.8–7000 mIU/ml	39.5

Dr. Rajesh B. Goel
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Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
			HAEMATOLOGY & IMMUNOHAEMATOLOGY		
1.	Whole Blood	Hemoglobin	Photometric	0 – 22.5 gm/dl 0 – 30 gm/dl	2.6
2.	Whole Blood	WBC Count	Optical	0.02 – 400 x 10^3/ul 0.3 – 99.9 x 10^3/ul	10.0
3.	Whole Blood	RBC	Optical	0 – 7.0 x 10^5/cmm 0.2 – 9.99 x 10^6/cmm	5.8
4.	Whole Blood	HCT	Calculated	100 %	8.5
5.	Whole Blood	MCV	Calculated	200 %	5.2
6.	Whole Blood	MCH	Calculated	0.00 – 99.00 pg	6.8
7.	Whole Blood	MCHC	Calculated	0.00 – 99.00 gldl	8.9
8.	Whole Blood	Platelet Count	Optical	5.0 – 3500 x 10^3/uL	9.3
		Polymorphs	Flowcytometry	0-100 %	5.7
		Lymphocytes	Flowcytometry	0-100 %	6.4
		Monocytes	Flowcytometry	0-100 %	6.9
		Eosinophils	Flowcytometry	0-100 %	23.0
9.	Whole Blood	Peripheral Smear For Morphology	Manual Microscopy (Field/Leishman Stain)	NA	NA

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Program Manager

महाराष्ट्र शासन

सार्वजनिक आरोग्य विभाग

शासन निर्णय क्रमांकः माअप्र-२०१८/प्र.क्र.२२०/आरोग्य-६

गो.ते.रुग्णालय आवार संकुल इमारत,
१०वा मजला, नवीन मंत्रालय, मुंबई-०१

दिनांक: ०७ डिसेंबर, २०१८

वाचा :-

१) वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग, अधिसूचना क्र. SWP-०४१४/C.R.०८/Acts, दिनांक ३०.०६.२०१८

२) समुचित प्राधिकारी (माअप्र) तथा संचालक, आरोग्य सेवा संचालनालय, मुंबई यांचे पत्र क्र. संआसे/माअप्र/लोकलऑथोकमिट/नामनिर्देशितप्रतिनिधी/७६३/२०१८,दिनांक ३०.११.२०१८

प्रस्तावना :-

वैद्यकीय शिक्षण व औषधी द्रव्ये विभागाच्या संदर्भाधिन क्र. १ येथील दिनांक ३०.०६.२०१८ च्या अधिसूचनेन्वये १६ रूग्णालयांमध्ये मानवी अवयव व उती प्रत्यारोपण अधिनियम, १९९४ अंतर्गत Hospital Based Authorization समिती गठीत करण्यात आलेली आहे. सदर समितीमध्ये अ.क्र.६ येथे अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग किंवा त्यांचे Nominee यांचा समितीचे सदस्य म्हणून समावेश करण्यात आला आहे. संदर्भाधिन क्र. २ येथील संचालक, आरोग्य सेवा यांचेकडून प्राप्त प्रस्तावास अनुसरून मानवी अवयव प्राधिकार समितीच्या बैठकांना उपस्थित राहण्याकरीता अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग व संचालक, आरोग्य सेवा यांचे प्रतिनिधी नामनिर्देशित करण्याची बाब शासनाच्या विचाराधीन होती.

शासन निर्णय:-

मानवी अवयव व उती प्रत्यारोपण अधिनियमांतर्गत गठीत Hospital Based Authorization समितीच्या बैठकांना उपस्थित राहण्याकरीता अपर मुख्य सचिव/प्रधान सचिव/सचिव, सार्वजनिक आरोग्य विभाग व संचालक, आरोग्य सेवा यांचे प्रतिनिधी म्हणून खालीलप्रमाणे नामनिर्देशित करण्यात येत आहे.

अ.क्र.	रूग्णालयाचे नाव	अपर मुख्य सचिव/ प्रधान सचिव/ सचिव (सा.आ.वि.) यांचे प्रतिनिधी	संचालक, आरोग्य सेवा यांचे प्रतिनिधी
१	बॉम्बे हॉस्पीटल,मुंबई	वैद्यकीय अधिक्षक, सामान्य रूग्णालय, मालवणी, मालाड, मुंबई	सहायक संचालक, ठाणे
२	जसलोक हॉस्पीटल,मुंबई		
३	पी.डी.हिंदुजा हॉस्पीटल, माहिम, मुंबई		
४	व्होकार्ड हॉस्पीटल,मुंबई सेंट्रल, मुंबई		
५	कोकीलाबेन धिरूभाई अंबानी		

	हॉस्पीटल, अंधेरी, मुंबई		
६	ग्लोबल हॉस्पीटल, परेल, मुंबई	वैद्यकीय अधिक्षक,मनोरूग्णालय,ठाणे	अतिरिक्त जिल्हा शल्य चिकीत्सक, जिल्हा रूग्णालय, ठाणे
७	फोर्टीस हॉस्पीटल, मुलुंड, मुंबई		
८	ज्युपिटर हॉस्पीटल, ठाणे		
९	अपोलो हॉस्पीटल, बेलापूर, नवी मुंबई	वैद्यकीय अधिक्षक, उपजिल्हा रूग्णालय, पनवेल	जिल्हा शल्य चिकीत्सक, जिल्हा रूग्णालय, ठाणे
१०	आदित्य बिर्ला हॉस्पीटल, चिंचवड, पुणे	सहायक संचालक,पुणे	जिल्हा शल्य चिकीत्सक, जिल्हा रूग्णालय, औंध, पुणे
११	दिनानाथ मंगेशकर हॉस्पीटल, एरंडवणे, पुणे		
१२	सहयाद्री हॉस्पीटल, एरंडवणे, पुणे		
१३	जहांगीर हॉस्पीटल, ससून रोड, पुणे	वैद्यकीय अधिक्षक, मनोरूग्णालय, पुणे	अतिरिक्त जिल्हा शल्य चिकीत्सक, जिल्हा रूग्णालय, पुणे
१४	रूबी हॉल क्लिनिक, ससून रोड,पुणे		
१५	कमलनयन बजाज हॉस्पीटल, औरंगाबाद	सहायक संचालक, औरंगाबाद	जिल्हा शल्य चिकीत्सक, जिल्हा रूग्णालय, औरंगाबाद
१६	एमजीएम हॉस्पीटल, औरंगाबाद		

२. सदर शासन निर्णय महाराष्ट्र शासनाच्या www.maharashtra.gov.in या संकेतस्थळावर उपलब्ध करण्यात आला असून त्याचा सांकेताक 201812071439599217 असा आहे. हा आदेश डिजीटल स्वाक्षरीने साक्षांकित करुन काढण्यात येत आहे.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने,

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

(सु.नि.गाडगे)
कार्यासन अधिकारी, महाराष्ट्र शासन

प्रत,

१) मा. राज्यपाल यांचे सचिव, राजभवन, मुंबई
२) मा. मुख्यमंत्री यांचे प्रधान सचिव, मंत्रालय, मुंबई
३) मा.मंत्री (सार्वजनिक आरोग्य व कुटुंब कल्याण) यांचे खाजगी सचिव, मंत्रालय, मुंबई
४) मा. राज्यमंत्री (सार्वजनिक आरोग्य व कुटुंब कल्याण) यांचे खाजगी सचिव, मंत्रालय, मुंबई
५) मुख्य सचिव, महाराष्ट्र राज्य, मंत्रालय, मुंबई

६) प्रधान सचिव, सार्वजनिक आरोग्य विभाग, नवीन मंत्रालय, मुंबई

७) प्रधान सचिव, विधि व न्याय विभाग, मंत्रालय, मुंबई

८) सचिव, वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग, नवीन मंत्रालय,मुंबई

९) आयुक्त, आरोग्य सेवा तथा अभियान संचालक, राष्ट्रीय आरोग्य अभियान, मुंबई

१०) विधि सल्लागार-नि-सहसचिव, विधि व न्याय विभाग, मंत्रालय, मुंबई

११) संचालक, आरोग्य सेवा, आरोग्य सेवा संचालनालय, मुंबई

१२) संचालक, वैद्यकीय शिक्षण व संशोधन संचालनालय, मुंबई

१३) जिल्हाधिकारी (सर्व)

१४) सहसंचालक, आरोग्य सेवा (रूग्णालये/राज्यस्तर), आरोग्य सेवा संचालनालय,मुंबई

१५) सहसंचालक, आरोग्य सेवा (सर्व)

१६) उपसंचालक, आरोग्य सेवा परिमंडळे (सर्व)

१७) सहायक संचालक (माअप्र), आरोग्य सेवा संचालनालय, मुंबई.

१८) जिल्हा शल्यचिकित्सक (सर्व)

१९) निवड नस्ती (आरोग्य -६)

RNI No. MAHBIL /2009/31733

महाराष्ट्र शासन राजपत्र

असाधारण भाग चार–अ

वर्ष ४, अंक ८०] शनिवार, जून ३०, २०१८/आषाढ ९, शके १९४० [पृष्ठे ७, किंमत : रुपये १५.००

असाधारण क्रमांक १३३

प्राधिकृत प्रकाशन

महाराष्ट्र शासनाने केंद्रीय अधिनियमांन्वये तयार केलेले
(भाग एक, एक-अ आणि एक-ल यांमध्ये प्रसिद्ध केलेले नियम व आदेश यांव्यतिरिक्त) नियम व आदेश.

MEDICAL EDUCATION AND DRUGS DEPARTMENT

New Mantralaya, 9th floor, GokuldasTejpal Hospital Complex,
LokmanyaTilak Road, Mumbai 400 001, dated the 30th June 2018.

NOTIFICATION

TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ACT, 1994.

No. SWP-0414/C.R.08/Acts.—In exercise of the powers conferred by clause (*b*) of sub-section (*4*) of section 9 of Transplantation of Human Organs and Tissues Act, 1994 (42 of 1994) read with rules 11 and 12 of the Transplantation of Human Organs and Tissues Rules, 2014, and of all other powers enabling it in that behalf and in supersession of all earlier notifications, orders or instruments issued in this behalf, the Government of Maharashtra, hereby, constitutes, the Hospital Based Authorization Committees, for the hospital in which more than 25 transplantations have been made as specified in the Schedule appended hereto and also appoints the Chairperson and Members thereof as specified in the Schedule, for the purposes of the said Act and rules made thereunder, as follows, namely :—

Schedule

(1) Hospital Based Authorization Committee at **Bombay Hospital, Marine Lines, Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Rajkumar Patil
2	Member under clause (*b*) of Rule 12	Dr. Kapil Salagia
3	Member under clause (*b*) of Rule 12	Dr. Suresh Jain

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
4	Member under clause (*c*) of Rule 12	Dr. Smt. Sunita Kshirsagar.
5	Member under clause (*c*) of Rule 12	Dr. Vijay Punjabi
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nomineer.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(2) Hospital based Authorization Committee at **Fortis Hospital, Mulund, Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. S. Narayani
2	Members under clause (*b*) of Rule 12	Dr. Pravin Shah
3	Members under clause (*b*) of Rule 12	Dr. Sandeep Gore
4	Member under clause (*c*) of Rule 12	Dr. Smt. Jesal Sheth
5	Member under clause (*c*) of Rule 12	Dr. Ramesh Punjani
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(3) Hospital based Authorization Committee at **Global Hospital, Parel, Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Jigna Shortriya
2	Member under clause (*b*) of Rule 12	Dr. Rajiv Nikte
3	Member under clause (*b*) of Rule 12	Dr. Nirupa Borges
4	Member under clause (*c*) of Rule 12	Dr. Smt. Kajal Ahuja
5	Member under clause (*c*) of Rule 12	Dr. Pragji Vaja
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(4) Hospital based Authorization Committee at **Jaslok Hospital, Pedar Road, Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Lalita Delima
2	Member under clause (*b*) of Rule 12	Dr. Minal Shah
3	Member under clause (*b*) of Rule 12	Dr. Ravindra Bendre
4	Member under clause (*c*) of Rule 12	Dr. Smt. Usha Shah
5	Member under clause (*c*) of Rule 12	Dr. Anil Pachnekar
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(5) Hospital based Authorization Committee at **Kokilaben Ambani Hospital, Andheri (West), Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Ram Narayn
2	Member under clause (*b*) of Rule 12	Dr. Jotsna Oak
3	Member under clause (*b*) of Rule 12	Dr. Manohar Kamat
4	Member under clause (*c*) of Rule 12	Dr. Smt. Alka Rao
5	Member under clause (*c*) of Rule 12	Dr. Suraj Suchak
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(6) Hospital based Authorization Committee at **P. D. Hinduja Hospital, Mahim (West), Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Sugandhi Iyer
2	Member under clause (*b*) of Rule 12	Dr. S. V. Prabhu
3	Member under clause (*b*) of Rule 12	Dr. C. V. Vanjani
4	Member under clause (*c*) of Rule 12	Dr. Mrs. Prarthana Utture
5	Member under clause (*c*) of Rule 12	Dr. Sudhir Patil
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(7) Hospital based Authorization Committee at **Wockhardt Hospital, Mumbai Central, Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Parag Rindani
2	Member under clause (*b*) of Rule 12	Dr. Bchram Pardiwalla
3	Member under clause (*b*) of Rule 12	Dr. Dipti Patel
4	Member under clause (*c*) of Rule 12	Dr. Smt. Sujatunnisa Attar.
5	Member under clause (*c*) of Rule 12	Dr. Salim Sachani
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(8) Hospital based Authorization Committee at **Jupiter Hospital, Thane** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Ravindra Karnjekar
2	Member under clause (*b*) of Rule 12	Dr. Pankaj Joshi
3	Member under clause (*b*) of Rule 12	Dr. Nikhil Kamat
4	Member under clause (*c*) of Rule 12	Dr.Smt. Manjushri Vivek Birla.
5	Member under clause (*c*) of Rule 12	Dr. Mahesh Bedekar
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(9) Hospital based Authorization Committee at **Apollo Hospital, Navi Mumbai** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Narendra Trivedi
2	Member under clause (*b*) of Rule 12	Dr. Sobati Shyam
3	Member under clause (*b*) of Rule 12	Dr. Vishal Malhotra
4	Member under clause (*c*) of Rule 12	Dr. Smt. Alka Patnaik
5	Member under clause (*c*) of Rule 12	Dr. Gangadhar Maheshwari.

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(10) Hospital based Authorization Committee at **Aditya Birla Hospital, Pune** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Ashutosh Shrivastava
2	Member under clause (*b*) of Rule 12	Dr. Rahul Kallianpur
3	Member under clause (*b*) of Rule 12	Dr. Sandeep Bhavsar
4	Member under clause (*c*) of Rule 12	Dr. Smt. Pratibha Kane
5	Member under clause (*c*) of Rule 12	Dr. Raju Varyani
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(11) Hospital based Authorization Committee at **Deenanath Mangeshkar Hospital, Pune** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Utkrant Kurlekar
2	Member under clause (*b*) of Rule 12	Dr. Asmita Bhave
3	Member under clause (*b*) of Rule 12	Dr. Jayant Agate
4	Member under clause (*c*) of Rule 12	Dr. Smt. Maya Tulpule
5	Member under clause (*c*) of Rule 12	Dr. Jayant Navarange
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(12) Hospital based Authorization Committee at **Sahyadri Super Specialty Hospital, Pune** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Deepa Divekar
2	Member under clause (*b*) of Rule 12	Dr. Jayshree Apte
3	Member under clause (*b*) of Rule 12	Dr. Dhananjay Chandkkar.
4	Member under clause (*c*) of Rule 12	Dr. Smt. Aarti Nimkar
5	Member under clause (*c*) of Rule 12	Dr. B. L. Deshmukh
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(13) Hospital based Authorization Committee at **Ruby Hall Clinic, Pune** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Sanjay Pathare
2	Member under clause (*b*) of Rule 12	Dr. N. C. Ydul
3	Member under clause (*b*) of Rule 12	Dr.C.P.Bajpai
4	Member under clause (*c*) of Rule 12	Dr. Smt. Padma Iyer
5	Member under clause (*c*) of Rule 12	Dr. Rajkumar Shah
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(14) Hospital based Authorization Committee at **Jahangir Hospital, Pune** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. N. G. Kamat
2	Member under clause (*b*) of Rule 12	Dr. Uma Divate
3	Member under clause (*b*) of Rule 12	Dr. Milind Botre
4	Member under clause (*c*) of Rule 12	Dr. Smt. Meenakshi Deshpande.
5	Member under clause (*c*) of Rule 12	Dr. Arun Haibe
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(15) Hospital based Authorization Committee at **Kamalnayan Bajaj Hospital, Aurangabad** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Alok Shrivastav
2	Member under clause (*b*) of Rule 12	Dr. S. P. Ekbote
3	Member under clause (*b*) of Rule 12	Dr. R. B. Sharma
4	Member under clause (*c*) of Rule 12	Dr. Smt. Ujwala Dahipale.
5	Member under clause (*c*) of Rule 12	Dr. Santosh Ranjalkar
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee.	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee.	Member.

(16) Hospital based Authorization Committee at **M. G. M. Hospital, Aurangabad** consisting of following Members :—

Sr. No. (1)	Rule (2)	Chairperson / Members (3)
1	Chairperson under clause (*a*) of Rule 12	Dr. Aparna Kakkad
2	Member under clause (*b*) of Rule 12	Dr. S. H. Talib
3	Member under clause (*b*) of Rule 12	Dr. S. A. Sami
4	Member under clause (*c*) of Rule 12	Dr. Smt. Rashmi Borikar.
5	Member under clause (*c*) of Rule 12	Dr. Yashwant Gade
6	Member under clause (*d*) of Rule 12 Additional Chief Secretary/ Principal Secretary/ Secretary Public Health Department or his nominee	Member
7	Member under clause (*d*) of Rule 12 Director of Health Service or his nominee	Member.

Note.—Terms and conditions of Chairperson and Members of Hospital based Authorization Committees :—

(*1*) Each member of Authorization Committee shall have equal power.

(*2*) No official members of Authorization Committee shall be entitled to Travelling Allowance and Daily Allowance as admissible to Group A members of State Government.

(*3*) The Quorum of the Authorization Committee shall be minimum four and the quorum should not be complete without the participation of the Chairperson, the presence of Secretary (Health) or nominee and Director of Health Services or his nominee.

By order and in the name of the Governor of Maharashtra,

SURENDRA P. CHANKAR,
Deputy Secretary to Government.

ON BEHALF OF GOVERNMENT PRINTING, STATIONERY AND PUBLICATION, PRINTED AND PUBLISHED BY I/C DIRECTOR SHRI MANOHAR SHANKAR GAIKWAD, PRINTED AT GOVERNMENT CENTRAL PRESS, 21-A, NETAJI SUBHASH ROAD, CHARNI ROAD, MUMBAI 400 004 AND PUBLISHED AT DIRECTORATE OF GOVERNMENT PRINTING, STATIONERY AND PUBLICATIONS, 21-A, NETAJI SUBHASH ROAD, CHARNI ROAD, MUMBAI 400 004 EDITOR : I/C DIRECTOR SHRI MANOHAR SHANKAR GAIKWAD.

List of IMA Members Hospital Based Authorization Committee with their Mobile Numbers

Sr. No.	Name of Hospital	Name of IMA Members with Mobile Numbers	
1.	Bombay Hospital, Mumbai	1.Dr.Sunita Kshirsagar 2. Dr.Vijay Panjabi	9820118181 9821061205
2.	Global Hospital, Parel Mumbai	1. Dr.Smt. Kajal Ahuja 2. Dr. Pragji Vaja	9833110302 9820482375
3.	Jaslok Hospital, Mumbai	1. Dr. Smt Usha Shah 2. Dr. Anil Pachnekar	9322004145 9869001873
4.	P.D.Hinduja Hospital, Mahim	1. Dr. Smt. Prarthana Utture 2. Dr. Sudhir Patil	9833556069 982030353
5.	Wockhardt Hospital, Bombay Central	1. Dr. Smt.Sujatunnisa Attar 2. Dr. Salim Sachani	7506033993 9892631484
6.	Kokilaben Ambani Hospital,Andheri	1. Dr. Smt. Alka rao 2. Dr. Suraj Suchak	9820338360 9920080151
7.	Fortis Hospital, Mulund	1. Dr. Smt.Sejal Sheth 2. Dr. Ramesh Punjani	9930951440 9819327833
8.	Appolo Hospital Washi	1. Dr. Smt.Alka Patnaik 2. Dr. Gangadhar Maheshwari	9323170532 9820011036
9.	Jupiter Thane	1. Dr.Smt.Manjushri Vivek Birla 2. Dr.Mahesh Bedekar	9930140355 9821913638
10.	Aditya Birala Hospital,Pune	1. Dr.Smt.Pratibha Kane 2. Dr.Raju Vayani	9822090771 9822646025
11.	Deenanath Mangeshkar Hosp.	1. Dr.Smt.Maya Tulpule 2. Dr.jayant Navrange	9823709210 9561081674
12.	Sahaydri Super specility Hosp,Pune	1. Dr.Aarti Nimkar 2. Dr.B.L.Deshmukh	9822304882 9960172759
13.	Jahangi Hospital, Pune	1. Dr.Meenakshi Deshpande 2. Dr.Arun Halbe	9922464365 9423586343
14.	Ruby Hall clinic	1. Dr.Padma Iyer 2. Dr.Rajkumar Shah	9373305154 9422500666
15.	Kamalnayan Bajaj Hosp,Aurangabad	1. Dr.Smt.Ujwala Dahiphale 2. Dr.Santosh Ranjalkar	
16.	M.G.M.Hosp, Aurangabad	1. Dr.Smt.Rashmi Borikar 2. Dr.Yashwant Gade	

INDIAN RESUSCITATION COUNCIL

authorizes

M.G.M.MEDICAL COLLEGE AND HOSPITAL,AURANGABAD

located at

N-5 CIDCO Aurangabad, Aurangabad-Maharashtra 431003 India

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

as its
Comprehensive Resuscitation Training Centre (CRTC)

to conduct its resuscitation courses for the period

21 Aug 2018 **to** **21 Aug 2020**

Dr.SSC Chakrarao
Chairman
Indian Resuscitation Council

ICTC Centre, MGMH, Kamothe Navi Mumbai

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

28 FEB 2013

पुरवठ्याचा दिनांक
उपकोषागाराचे नांव-पनवेल,
जि. रायगड.

उपकोषागार अधिकारी
पनवेल - रायगड.

स्टॅम्प वेंडर
क्र. 132/2013 दिनांक 1/3/2013
नाव C.M. जी.एम. मेडिकल हॉस्पिटल - कामोठे
माया काळे
राजपूरकर

GC 963458

TRIPARTITE AGREEMENT FOR SERVICE DELIVERY ON INTEGRETED COUNSELING AND TESTING CENTRES (ICTCs)

Memorandum of understanding (MOU)
Between
National AIDS Control Organization (NACO)
Government of India
&
MGM Medical College and Hospital, Kamothe, Navi Mumbai

Dean
MGM Medical College, Navi Mumbai
Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

This Memorandum of Understanding is made on day of April 2013 by and between the director General, National AIDS Control Organization, Department of Health, Ministry of Health and Family Welfare, Government of India, 9th & 6th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (herein referred to as "NACO") through the Project Director of Maharashtra State AIDS control Society, (hereafter referred to as "MSACS"), Shri Prakash Safde, I.A.S. Project Director, Acworth complex, R.A.Kidwai Marg, Wadala, Mumbai – 400031.

MGM Medical College and Hospital, a facility having its office at Kamothe Navi Maumbai Raigad, acting through Dr. P. P. Doke, the authorized signatory, hereinafter referred to as **MGM Medical College and Hospital**, which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

I. PURPOSE OF THE COLLABORATIVE PROJECT

The purpose of the agreement is to set up NACO certified facility integrated counseling and testing centre for HIV counseling and testing in a private sector/not for profit/non governmental organizations run health facility through a public private partnership. The aim is to provide access to quality HIV counseling and testing services to clients who access private/ not for profit health care system in both urban and rural areas of the country.

II RESPONSIBILITIES OF THE SACS.

1. To supply rapid HIV diagnostic kits (3 different antigens/ principles) in quarterly advance as per annual requirement to **MGM Medical College and Hospital**, subject to availability of above kits with SACS. While every effort will be made to provide uninterrupted supply of above kits, SACS will not held responsible for any shortage of above kits due to unforeseen circumstances.

2. To provide training of staff of ICTC (staff of facility) in HIV counseling and testing in NACO approved centers. If required more than one training will be provided by the SACS.

3. To supply protective kits for delivery of HIV positive pregnant woman as per requirement to if needed.

4. To provide TA/DA a per eligibility to ICTC staff of **MGM Medical College and Hospital**, for attending review meeting conducted by SACS as well as for collecting the HIV test kits, registers, formats etc. from the office of the SACS and for transport of coded blood sample or delivery of blood test records from **MGM Medical College and Hospital**, to the SRL (State References Laboratory-State/ district ICTC management authority) under the external quality assurance schemes (EQAS) as laid out in "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt of India in July, 2007 or any newer version thereof

5. To supply PEP (Post-exposure Prophylaxis) drugs for protection of staff of ICTC in the event of accidental exposure to **MGM Medical College and Hospital**, as per requirement.

6. To supply IEC material required for an ICTC such as flip charts, posters, condom demonstration models, take home materials to **MGM Medical College and Hospital**, as per requirement.

7. To Supply condoms required for demonstration and distribution to clients coming to the ICTC as per requirement.

8. To supply prophylactic ARV drugs for prevention of transmission from HIV positive mother to their new born babies as per national protocol.

9. To evaluate the performance of the ICTC periodically as per monitoring and evaluation tools developed by NACO/SACS.

10. To provide Registers and Formats as per "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health and Family Welfare, Govt. of India in July, 2007 or any newer version thereof.

III. RESPONSIBILITIES OF MGM MEDICAL COLLEGE AND HOSPITAL, KAMOTHE

1. To provide a room with suitable, sufficient and convenient space to be used for counseling purpose with adequate furniture, lighting and privacy and any other infrastructure required.

2. To provide a laboratory equipped with refrigerator, centrifuge, micropipette, needle cutter, etc for HIV testing and blood sample storing facility.

3. To designate existing staff or appoint new staff for the posts of counselor and laboratory technician in the ICTC. To also designate an existing Medical Officer as ICTC Manager.

4. To provide consumables such as needles, gloves, syringes, serum storage vials, micro tips, etc. of standard quality required for HIV testing to the ICTC.

5. To provide counseling and testing services in the ICTC to any client who approaches the ICTC without discrimination either freely **or on receipt of charge not exceeding** Rs. 75/- as per protocol laid out in the guideline text per "Operational guidelines for integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. The charge will be used to defray cost for provision of the above services.

6. To entirely bear the costs related to staff salary, infrastructure and consumables required for the ICTC.

7. To respect the privacy of clients and maintain confidentially. Provide data protection systems to ensure that records of all those who are counseled and tested are not accessible to any unauthorized person.

8. To maintain quality assurance at the services delivery especially in HIV testing services as provided in the guideline text "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. MGM Medical College and Hospital will be accountable for any substandard delivery of service.

9. To participate in EQAS (External Quality Assessment Scheme) as laid out in the above mentioned guideline text. MGM Medical College and Hospital will send samples in the first week of every quarter, for cross checking to SRL (State reference laboratory-state/ district management authority) once every quarter. The laboratory technician designated by MGM Medical College and Hospital to ensure that these samples are collected in the first week of January, April, July and October & sent to the SRL.

10. To provide data and information to the coordinating agency to perform their duties as per the instruction and direction from SACS.

11. To send monthly report to the SACS/DAPCU in CMIS format by 5th of every month in registers and records supplied by the SACS.

12. To use all the IEC materials, condoms, items required for laboratory use, protective kits for delivery, PEP (post exposure prophylaxis) drugs supplied by the SACS at the services delivery purpose by the MGM Medical College and Hospital.

13. To Maintain stock records for the all items and drugs provided by the SACS.

14. To maintain quality waste management of disposable items that is used in HIV testing.

15. To ensure that ICTC staff working in the blood collection room and laboratory will observe universal safety precaution (USP).

16. To ensure that ICTC staff are aware of the PEP procedure and display the name and contact information of the PEP focal point/ person as well as the location where the PEP drugs are stored.

17. To follow the national protocol for ARV prophylaxis for prevention of parent to child transmission of HIV (PPTCT).

18. To attend coordination/ review meetings conducted by SACS.

19. To ensure that no research or clinical trials are done on the clients who visit the ICTC or based on data of clients who visits the ICTCs.

20. To attend review meetings at the district level and SACS level as per the supervisory protocol that is provided in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. To allow access to authorized NACO/SACS/DAPCU staffs who visit the ICTC to the premises and records of the ICTC.

21. To permit SACS to periodically test designated counselor and Lab Technician for their knowledge, attitude and skills.

22. To follow the testing methodology & algorithm as mention in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof, in the laboratory of **MGM Medical College & Hospital.**

23. To follow National AIDS Control Policy & State HIV/AIDS policy.

24. Test kits supplied by MSACS not to be used for routine screening of surgical patients of the facility.

IV. COMMENCEMENT

1) This Memorandum of Understanding shall become effective upon signature by the parties and certification of the facility site. It shall remain in full force and effect for a period of one year thereafter.

2) Further, the certification of the site of the collaborative testing project as "NACO/SACS designated HIV counseling and testing centre" shall run concomitantly with the present Memorandum of Understanding.

3) SAATHII, the implementing partner, authorized by MSACS will support the private sector on commencement and closely coordinate for smooth rollout.

V. RENEWAL OF AGREEMENT

1) This Memorandum of Understanding is renewable at the option of MSACS.

2) Three months prior to the expiry of the Memorandum of Understanding due to efflux of time SACS shall intimate **MGM Medical College & Hospital** if it intends to renew or not to renew the Memorandum of Understanding.

3) In the event that SACS decides not to renew the Memorandum of Understanding, **MGM Medical College & Hospital** hall give notice to the patients regarding the cancellation of its certification. In the event that SACS decide to renew the Memorandum of Understanding, the terms and conditions of this Memorandum of Understanding, as may be amended, will apply *de novo*.

VI. TERMINATION OF AGREEMENT

1) Any party may terminate this Memorandum of Understanding after giving three months notice to the other party at the address provided in this Memorandum of Understanding for correspondence or the last communicated for the purpose and acknowledges in writing by other party.

VII. BREACH BY MGM MEDICAL COLLEGE AND HOSPITAL

1) In case **MGM Medical College & Hospital** is not able to provide services as per agreement of defaults on the provision of this agreement or declines the patient to provide HIV counseling and testing services, it shall be liable for breach of agreement and breach of trust and other

VII. BREACH BY MGM MEDICAL COLLEGE AND HOSPITAL

1) In case **MGM Medical College & Hospital** is not able to provide services as per agreement of defaults on the provision of this agreement or declines the patient to provide HIV counseling and testing services, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with SACS, NACO, MOHFW of Home affairs and external affairs.

IX. SETTLEMENT OF DISPUTES:

1) Any dispute of difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this agreement shall be referred to and settled by arbitration under the provision of the Indian Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.

2) The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India, Delhi. The arbitrator, if he so feels necessary, seek opinion of any healthcare personnel with experience of working in the field of HIV and care and treatment of PLHAs.

3) The place of arbitration shall be either New Delhi or the site of the collaborative laboratory, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.

4) The decision of the arbitrator shall be final and biding on both the parties.

X. LAW APPLICABLE

This Memorandum of Understanding shall be construed and governed in accordance with the laws of India

XI. ADRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed For and on behalf of MGM Medical College and Hospital

Dr. P. P. Doke
Med. Supdt.
MGM Medical College and Hospital

Signature.....
Date.....7/3/2012.....Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

In the presence of .....
Name.....

Signature
.....

Date.....

Signed for and on behalf of NACO

Project Director

MSACS

Signature.....

Date .....

In the presence of

Name Dr Tejaswini Khandapurkar

Signature.....Khandapurkar

Date.....8/3/2012

District Programme Officer
DAPCU Thane

District Programme Officer
DAPCU Thane

महाराष्ट्र MAHARASHTRA ◐ 2016 ◐ AB 905158

- 8 NOV 2017

MEMORANDUM OF UNDERSTANDING

Between

Chief executive officer, Zila Parishad Raigad & District Revised National Tubersulosis Control Programme society, District Raigad

AND

MGM Medical College Hospital, Kamothe

This MOU is executed on 15th December 2017 between **Chief executive officer, Zila Parishad Raigad & District Revised National Tubersulosis Control Programme society, District Raigad** having its office at In front of Civil Hospital, Alibag (Hereinafter called **"the Grantor"** which expression shall unless excluded by or repugnant to the context include its successors in-interest, executors, administrators and legal representatives) And **MGM MEDICAL COLLEGE**

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

जोड पत्र –2/Annexure-II

अ. क्र. 1815 मु. शु. रक्कम 500/- दि. 16/11/2017

दस्ताचा प्रकार MOU.

दस्त नोंदणी करणार आहेत का : होय / नाही

मिळकतीचे थोडक्यात वर्णन _____

मुद्रांक विकत घेणाऱ्याचे नाव MGM Medical College & Hospital.

दुसऱ्या पक्षकाराचे नांव District Tuberculosis Office Raigad

हस्ते व्यक्तीचे नाव व पत्ता Vishal

मुद्रांक विकत घेणाऱ्याची सही

सौ. घनश्री एस. बोंद्रे

ऑफिस नं.1, साईशरण कॉम्प्लेक्स,
पेठ मजला, सेक्टर–8, खांदा कॉलनी,
न्यू पनवेल(प.) जि. रायगड.
परवाना क्र. –7 / 1996 –97

ज्या कारणासाठी त्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणांसाठी मुद्रांक खरेदी केल्यापासुन 6 महिन्यात वापरणे बंधनकारक आहे.

HOSPITAL, KAMOTHE hence forth referred to as PPP Partner, having its office at Plot No 1&2, Kamothe, Navi Mumbai acting through its Hereinafter called **"the Grantee"**, which expression shall unless excluded by or repugnant to the context include its successors it, interest, executors, administrators and legal representatives).

WHEREAS the Grantor plans to implement "RNTCP (Revised National TB Control Programme) ie DR TB center with Indoor & Outdoor facilities through Grantee on partnership (PPP partener).

AND WHEREAS the Grantor has agreed to engage the services of the Grantee, subject to terms and as hereunder.

1. **DRTB center (under):** The activities would be implemented in the District/s of **Raigad & Navi Mumbai , Maharashtra** for performance of the following activities in accordance with RNTCP policy;

2. Project Location

The PPP Partner would be providing the services as specified above at the following location/ (s) as decided in consultation with concerned CTO/DTO

a. Urban/ Rural: **Urban/ Rural**

b. District/ TU/ Block/ (s): **Raigad & Navi Mumbai**

c. Urban Wards/ Panchayats covered: Yes

d. Population Covered: App. 40 lacs

3. Period of Co-operation:

The PPP Partner agrees to perform all activities outlined in the guideline for partnerships in above mentioned area. The duration of cooperation will be from day signing of MOU or the day of the starting the activity / function whichever is later.

Contract is signed for a period of three year 15th December 2017 to 14th November 2020, renewable as per the needs of the programme, subject to satisfactory performance. The contract can be terminated by the District Health Society/ State Health Society or the PPP Partner any time with one month prior notice by either side.

4. Terms, conditions and specific services during the period of the MOU.

A. **The District Health Society shall** (please strike out whichever is not applicable)

i. Provide financial and material support to the PPP for carrying out the activities as mentioned in the partnership guideline.

Chief Executive Officer
Zilla Parishad,

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

ii. Provide relevant copy of technical guidelines, updates, manuals & circulars, etc.)

iii. Provide RNTCP drugs, logistics and laboratory consumables for use as per RNTCP policy as outlined the partnership guideline

iv. Periodically review the performance and activities being undertaken by the PP Partner

B. MGM will: -

i. Perform all activities as agreed upon and signed under the partnership as mentioned below.

Outdoor DRTB center Scheme:

1. Institute should be tertiary care hospital with the pulmonologist will be available round the clock.
2. Separate designated clinic for DR TB patient management should be available and comply with the National Guidelines for Air –borne infection control for out patient settings
3. Relevant specialists like Pulmonologist, Physician, Psychiatrist, Dermatologist & gynecologist etc should be available.
4. DR TB center Committee to be formed with the above group of doctors.
5. To renovate (in keeping with the National Airborne Infection Control Guidelines and National Guidelines for Programmatic Management of Drug Resistant TB (PMDT) provided for the purpose) and designate a special clinic area designated for MDR TB out patient service with earmarked well ventilated preferably open air waiting area separate from other waiting areas, away from clinics managing immune suppressed and venerable cases where the patients who will be eligible to avail DR TB services under RNTCP will be fast tracked , segregated and counseled in accordance with RNTCP guidelines.
6. Doctors and Nursing staff should be available from institute round the clock consultation services made available , if required by the patients.
7. Management of adverse drug reactions (ADRs) as per National PMDT Guidelines.
8. The diagnostics services to be provided by the partner organization would include at least.

Sl No	Investigations	Minimum No. of times test will be done	Rate for tests** (In Rs.)
1	Complete blood count	1	138
2	Blood sugar	1	25
3	LFT. OT/PT/Bilirubin	1	275
4	Blood Urea Nitrogen	1	55
5	Serum Creatinine	6	56
6	TSH	1	125
7	Urine routine & microscopy	1	39

Chief Executive Officer
Raigad Zilla Parishad, Alibag

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

8	Pregnancy test		69
9	Chest X ray	3	70
10	ECG	1	100

*Rates are based on rate of CGHS Delhi rates (per test) and are subject to revision as and when updated in CGHS website

Indoor DR TB Center scheme :

The terms and condition are as follows.

1. To designate a special ward compliant with national AIC guidelines and at least 10 beds earmarked for indoor management of DRTB patients according to National PMDT Guidelines.
2. Routine clinical laboratory investigation facility to be made available for pretreatment evaluation and monitoring.
3. Doctors and Nursing staff should be available from institute round the clock to the DRTB patients
4. Ancillary drugs to be provided as per DR TB center Committee's advised services / facilities to diagnose and manage adverse drug reaction (ARDs) as per National PMDT Guidelines.
5. Services /facilities to diagnose and manage the comorbid condition
6. Records and reports to be maintained for PMDT registration , follow up, referral and transfer (if required) \of patients as per guidelines update the same on the day basis using Nikshay
7. Quarterly reports to be submitted electronically
8. All doctors in the hospital should be following Standards fore TB care in India and notify all TB cases through Nikshay
9. Ensure coordination with implementing District officers and staff as well as laboratory for proper follow up of patients till outcome.
10. The diagnostics services to be provided by the partner organization would include at least.

Sl No	Investigations	Minimum No. of times test will be done	Rate for tests** (In Rs.)
1	Complete blood count	1	138
2	Blood sugar	1	25
3	LFT. OT/PT/Bilirubin	1	275
4	Blood Urea Nitrogen	1	55
5	Serum Creatinine	1	56
6	TSH	6	125
7	Urine routine & microscopy	1	39
8	Pregnancy test	1	69
9	Chest X ray	3	70
10	ECG	1	100
11	Indoor stay for maximum of 7days	1	
12	Food for maximum of days	1	

Chief Executive Officer

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

13	Specialist consultation	As required
14	Ancillary drugs for management \of adverse drug reaction and comrbidities	As required

11. The DR TB Centre cannot deny services to any eligible patient from the geographical area assign to the centre
12. This does not restrict the DR TB Centre from extending any further services to the patients, if clinically deemed necessary
13. DR TB Centre committee doctors will have to be trained in PMDT at National Level.
14. Management of MRD/XRD TB patients is to be done as per RNTCP Guidelines second line anti TB drugs will be provided from RNTCP.
15. The performance review of the PPM partner would be done bi annually and in case lack of satisfactory performance the contract may be terminated by either party with one month written notice

Gant-in-Aid

Fund shall be released by the respective health society in the name of the MGM for initial six months and subsequently biannually, within 30 days of the satisfactory completion activities and submission of required documents. The MGM will submit utilization certificate indicating expenditure during the particular quarter and available unspent balance to the respective State/District Health Society on quarterly basis. The subsequent release will depend on the unspent balance and committed liability (if any).

1. Remuneration for following posts on contractual basis will be provided :
   - Counselor –Rs.10,000/-pm
2. For diagnostic test of MRD –TB patients on outdoor basis, private partner would be reimbursed as per rates given above (applicable for area) by RNTCP.
3. In case ambulatory care of MRD TB patients Rs 200/day/per patients consultation charges would be applicable
4. Package cost per day for admitted MRD-TB cases will be Rs 800/- including pre treatment evaluation (as per list above),bed charges ,meals and ancillary drugs.
5. In house Specialist Consultation charges would be applicable at Rs 200/day/per patient for indoor patients.
6. For patients convenience, if he/she is partially or completely managed on ambulatory basis at the district level under guidance of DR TB Centre Committee
7. Rs 500/- per day if pre treatment investigation is done at the district level and patient is admitted to the ward hospital

Chief Executive Officer
Raigad Zilla Parishad, Alibag

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Dean.
M.G.M. Medical College & Hospita
Kamothe, Navi Mumbai - 41020

8. Rs 500/- one time for only DR TB Centre decision based on reports sent from the districts, if pre treatment investigation and treatment initiation is done at the district level in case patient refuses to get admitted. This will also be applicable if the district's request for follow up advise over email/phone/post on decision of DR TB Centre for either charges in regimen, adverse drug reaction management, co-morbidity management etc. without patient admission to the DR TB centre
9. In case of re-admission/ extension of stay due to cause /s secondary to TB or side effects of second line anti-TB drugs or co-morbidity management .
10. Charges up to Rs.800/day/patient(including bed and meals + investigations and ancillary drugs)
11. To provide Training, formats and registers for PMDT
12. To provide Computer and Internet Facility
13. To Provide access & training to NIKSHAY for online data management and patient tracking

6. Fund Management

Funds under this MOU shall be placed at the disposal of the Grantee in separate account opened by it, subject to its furnishing to the Grantor a letter of commitment containing such conditions as may be approved by the Grantor from the bank that the bank shall not exercise a lien over the said account or may right to set off or adjust any amount due to payable under any loan or credit arrangement which the Grantee may be having or may have with the bank against the amounts standing to the credit of the Grantee in the said amount.

The Grantee shall install and maintain separate books of accounts on cash basis accounting along with proper vouchers for expenditure incurred and with details of outstanding liabilities, if any. The Grantor shall have the right to inspect by its authorized officers of independent agencies the books of accounts and other records relating to the project fund kept by the Grantee any time during the agreement period or thereafter.

7. Grievance Redressal Mechanism

All grievances will be addressed within a period of thirty days. by DTO of the concerned district. Final decision will rest with district Health Societies. Annual review would be a platform for addressing grievance of PPM partners.

8. Right over Information/data

All documents, information, statistics and data collected by the Grantee in the discharge of the obligation under the MOU incidental or related to it (whether or not submitted to the Grantor) shall be the joint property of the Grantor, and the Grantee

Chief Executive Officer
Raigad Zilla Parishad, Alibag

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

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M.G.M. Medical College & Hospita
Kamothe, Navi Mumbai - 41020

9. Indemnity

The Grantee hereby agrees to always keep the Grantor indemnified and harmless from all claims /demands / action and proceedings which may arise by reason of any activity undertaken by Grantee if the activity is not in accordance with the approved guidelines.

This MOU shall be enforceable in courts situated at [Mumbai, Maharashtra] ; any suit or application for enforcement of the above shall be filed in the competent court at Mumbai and no other district of Maharashtra or outside Maharashtra shall have any Jurisdiction in the matter

10. Termination Mechanism

The partnership may be terminated by either side through written notice of one month. In case services of PPM partner are discontinued, unspent balance, if any will be refunded by the partner.

If the Grantor at any stage decides that the Grantee has misutilised the amounts (or any part thereof) already received from the Grantor or has fraudulently claimed any covenants, stipulation or obligations hereunder a commits a breach of any of the terms, conditions or provision of this MOU on its part to be observed and performed, or it at any stage reasonable ground exist to apprehend the breach of the terms and condition of the MOU in future or that the continuance of this project

may be prejudiced or be in jeopardy he/she may revoke this MOU wholly or partially and ask the Grantee to refund the amount received till then along with interest accrues, if any after giving at least fifteen days' notice and an opportunity of being heard to the Grantee

11. The programmatic and financial review of the partnership will be conducted every quarter.

12. Necessary approval of State Health Society has been obtained: Yes

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Dr G S Narshetty
Dean
MGM Medical College & Hospital,
Kamothe, Navi Mumbai

Seal

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

28/12/17

Signature of authorised signatory
Chief executive officer, Zila Parishad
Raigad & District Revised National
Tubersulosis Control Programme
society, District Raigad

Seal

DIRECTORATE OF HEALTH SERVICES.
(MAHARASHTRA STATE)
Arogya Bhavan, St.George's Hospital Compound, P.D'Mello Road,
Mumbai-400 001.

आरोग्य सेवा संचालनालय
(महाराष्ट्र राज्य)
" आरोग्य भवन ", सेंट जॉर्जेस रुग्णालय आवार, पी.डिमेलो रोड, मुंबई- ४०० ००१

	दूरध्वनी	
कार्यालय	२२६२१०३१-३६	Website : http://maha-arogya.gov.in
संचालक (वैयक्तिक)	२२६२१००६	Email : dhs_2005@rediffmail.com
सहसंचालक (रुग्णालये-राज्यस्तर)	२२६११४७१	Email : miscell@rediffmail.com
सहसंचालक (प्राआकेंद्र-जिपस्तर)	२२६२०२४९	Fax No. 022-22621034 / 22620234 (DHS)
सहसंचालक (असंसर्गजन्य रोग)	२२६२११८६	022- 22679044(Hosp.)
सहसंचालक (खरेदी कक्ष)	२२६२६२८३	022-22622155(CAO)
सहसंचालक (अर्थ व आस्थापना)	२२६२६७५५	022-22703785(Control Room)
		022-22621047 (NCD)

3 & 6 3 2 4 1 15

क्र.संआसे/डायलेसीस/ प्रशिक्षण/कक्ष ३/२०१३
दिनांक - ४/०४/२०१३

प्रति,

१) विभाग प्रमुख,
नेफ्रॉलॉजी डिपार्टमेंट,
के.ई.एम. हॉस्पीटल मुंबई, बी.जे.एल.नायर रुग्णालय, जे.जे समूह रुग्णालय, बी.जे. वैद्यकिय महाविद्यालय पुणे, के.ई.एम रुग्णालय पुणे, सुपर स्पेशालिटी हॉस्पीटल नागपूर, (अंतर्गत जी.एम.सी.नागपूर), जी.एम.सी औरंगाबाद, एम.जी.एम औरंगाबाद, मिरज मेडिकल कॉलेज मिरज, वैद्यकिय अधिक्षक सुपर स्पेशालिटी हॉस्पीटल अमरावती व नाशिक

विषय:- राज्यातील जिल्हा रुग्णालये मधे सुरु करण्यात येणाऱ्या डायलेसीस युनिट मधील भिषक/वैद्यकिय अधिकारी /स्टॉफ नर्सेस/ डायलीसीस टेक्नीशियन यांना प्रशिक्षण देणेबाबत...

संदर्भ:- मा. संचालक डी.एम.ई.आर यांचे पत्र क्र.संवैशिवसं/संआसे/डायलेसीस/ तंत्रज्ञ/ प्रशिक्षण/४-३ दि.१५/२/२०१३.

उपरोक्त संदर्भाधिन विषयाव्दारे आपणास कळविण्यात येते की, राज्यातील सर्व जिल्हा रुग्णालये/ सामान्य रुग्णालये व उपजिल्हा रुग्णालय शेगांव व पंढरपूर/ नांदेड स्त्री रुग्णालय या ठिकाणी लवकरच डायलेसीस युनिटस सुरु करण्यात येणार आहेत. तत्पूर्वी या युनिट मधे कार्यरत होणाऱ्या सर्वांचे गुणवत्तापूर्ण प्रशिक्षण होणे गरजेचे आहे. या प्रशिक्षणाचा आराखडा ठरविणे तसेच प्रशिक्षणामध्ये समन्वयाच्या दृष्टीने नेफ्रॉलॉजी युनिट प्रमुख संबंधित हॉस्पीटलस यांची बैठक दिनांक १६/४/२०१३ रोजी दुपारी ३ वाजता आरोग्य सेवा संचालनालय, मुंबई (आठवा मजला,

[नि॰प.ध.अ./मुं.सा.वि./२ग.

No. 4401

सत्यमेव जयते

नोंदणी प्रमाणपत्र

याद्वारे प्रमाणपत्र देण्यात येते की, खाली वर्णन केलेली सार्वजनिक विश्वस्तव्यवस्था ही आज, मुंबई सार्वजनिक विश्वस्तव्यवस्था अधिनियम, १९५० (सन १९५० चा मुंबई अधिनियम २९) या अन्वये Aurangabad Region, Aurangabad येथील सार्वजनिक विश्वस्तव्यवस्था नोंदणी कार्यालयात योग्य रितीने नोंदण्यात आलेली आहे.

सार्वजनिक विश्वस्तव्यवस्थेचे नाव : Zonal Transplantation Coordination Center, Aurangabad.

सार्वजनिक विश्वस्तव्यवस्थांच्या नोंदणी पुस्तकातील क्रमांक : E - 1298 (A.bad)

Dr. Sudhir Gajanan Kulkarni यांस प्रमाणपत्र दिले.

आज दिनांक 12. 04. 2016 ~~२०१~~ रोजी माझ्या सहीनिशी दिले.

शिक्का : Assistant Charity Commissioner, Aurangabad Region, Aurangabad / सहायक धर्मादाय आयुक्त, औरंगाबाद विभाग, औरंगाबाद

सही 12/4/16

सहायक धर्मादाय आयुक्त

पदनाम औरंगाबाद विभाग, औरंगाबाद

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/820923-0
Purchase Order	202016253
Unit Reference	Polio/WR-India

DR.Jeetendra Gavhane
MGM'S NEW BOMBAY HOSPITAL FOR CHILDREN
NAVIMUMBAI
Plot no. 35, Sector No 3
Vashi
Navi Mumbai
Maharashtra
400703
India

TECHNICAL SERVICES AGREEMENT (TSA)

Re: MGM's New Bombay Hospital - To conduct hospital-based typhoid surveillance for the typhoid conjugate vaccine (TCV) evaluation project, Navi Mumbai, India 2018-19

We are enclosing the Technical Services Agreement between the World Health Organization and MGM'S NEW BOMBAY HOSPITAL FOR CHILDREN, NAVIMUMBAI, in the amount of INR 4,460,000.00 (Four Million Four Hundred Sixty Thousand), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical or scientific questions related to this Agreement, please contact the responsible technical officer, Pankaj BHATNAGAR, 91-9810189025, bhatnagarp@who.int.

On behalf of the World Health Organization, we thank you for your collaboration.

WHO Global Service Centre

Cc: WHO Representative, India

Concerne: MGM's New Bombay Hospital - To conduct hospital-based typhoid surveillance for the typhoid conjugate vaccine (TCV) evaluation project, Navi Mumbai, India 2018-19

Veuillez trouver ci-joint l'Accord de Services Techniques entre l'Organisation Mondiale de la Santé et MGM'S NEW BOMBAY HOSPITAL FOR CHILDREN, NAVIMUMBAI, pour un montant de INR 4,460,000.00 (Four Million Four Hundred Sixty Thousand), vous permettant de mener à bien le travail susmentionné. Veuillez également trouver two pièces jointes mentionnées dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

Pour toutes questions à caractère scientifique ou technique ayant trait à cet Accord, veuillez contacter le responsible technique Pankaj BHATNAGAR, 91-9810189025, bhatnagarp@who.int.

Au nom de l'Organisation Mondiale de la Santé, nous vous remercions de votre collaboration.

Centre de Soutien Administratif Mondial de l'OMS

Cc: Représentant de l'OMS, India

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/820923-0
Purchase Order	202016253
Unit Reference	Polio/WR-India

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
INSTITUTION:

MGM'S NEW BOMBAY HOSPITAL FOR CHILDREN
NAVIMUMBAI
Navi mumbai
India

Principal Investigator: DR.Jeetendra Gavhane
Telephone: +91 9870106094
Fax:
Email/Courriel: billing@mgmhospitalvashi.net

The Amount of/*Un Montant de*: INR 4,460,000.00 (Four Million Four Hundred Sixty Thousand)
in respect of/*en vue de:* MGM's New Bombay Hospital - To conduct hospital-based typhoid surveillance for the typhoid conjugate vaccine (TCV) evaluation project, Navi Mumbai, India 2018-19

For the period financed by this Agreement From/*De* : 13-JUN-2018
Période du projet *financée par le présent accord* To/*A* : 31-DEC-2019

Summary of work/ *Description sommaire des travaux:*

1. Description of work under this Agreement/ *Description des travaux faisant l'objet du présent accord:*

The contractual partner shall do the enrolment of potential subjects for the for the hospital-based typhoid surveillance for the typhoid conjugate vaccine (TCV) evaluation project, Navi Mumbai, India, as per Terms of Reference and Deliverables at Annex-1; Study Protocol at Appendix-1 and within the approved Budget at Annex-2. All the Annexes and Appendix form an integral part of this TSA.

During the course of the contract and on its completion the contractual partner shall submit the stipulated deliverables as indicated under the "Financial arrangements".

2. Contribution of the Institution and/or other sources for the project (Staff, equipment, supplies, etc. excluding general facilities). The Institute will provide all facilities, equipment and personnel not covered by this Agreement.
Contribution de l'Institution ou de tout autre organisme à l'exécution du projet (personnel, matériel, fournitures, etc, à l'exclusion des services d'ordre général). L'Institution s'engage à fournir les locaux, équipement et personnels non couverts par cet accord.

Financial Arrangements/ *Dispositions financiers:*

1. Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due Date/ *Date Remise*	%	Currency Amount/ *Montant en Devise*
1	Upon submission of countersigned contract	13-JUN-2018	50.00	2,230,000.00
2	A report of training conducted of all study staff	25-JUN-2018	25.00	1,115,000.00
3	6 monthly report on subject enrolment	30-DEC-2018	10.00	446,000.00
4	12 monthly report on subject enrolment	30-JUN-2019	10.00	446,000.00
5	Upon submission final technical document and Certified Financial Statement of Expenditure (SoE)	31-DEC-2019	5.00	223,000.00

2. INR 0.00 will be used by WHO for the purchase of equipment and supplies to be ordered by the Institution as soon as practicable, but not beyond 31 December of the year following the end of the Agreement period as indicated above at which time any uncommitted balance will revert to WHO.

INR 0.00 *seront affectés par l'OMS à l'achat de matériels et de fournitures à commander par l'Institution dès que possible, mais au plus tard avant le 31 décembre de l'année suivant la fin de la période susmentionnée d'exécution de l'accord, étant entendu qu'à ce moment tout solde non engagé fera retour à l'OMS.*

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de cet accord:*

Annex	File Description/Description de fichier
1	2018/820923 | Contractual - Terms of Reference |
2	2018/820923 | Contractual - Budget Breakdown |

In the event that the terms of the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les termes apparaissant sur les annexes et ceux de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/820923-0
Purchase Order	202016253
Unit Reference	Polio/WR-India

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

General

The parties accept the "General Conditions" overleaf, which constitute an integral part of this Agreement. The Institution certifies the correctness of the banking instructions provided on Page 1.

All necessary arrangements to comply with national regulations relating to this project and relevant to the Institution's responsibilities shall have been under-taken by the Institution; failure to do so will nullify this Agreement. The responsibility of the World Health Organization is limited only to the financial support as specified in this Agreement.

Généralités

Les parties acceptent les "Conditions générales" reproduites au verso, lesquelles font partie intégrante du présent accord. L'Institution certifie l'exactitude des instructions bancaires indiquées à la page 1.

Toutes les dispositions relevant des responsabilités de l'Institution et nécessaires à la mise en conformité de ce Projet avec la réglementation nationale, devront avoir été prises par l'Institution, faute de quoi l'accord sera nul. La responsabilité de l'Organisation Mondiale de la Santé se limite au soutien financier spécifié dans le présent accord.

ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Pankaj Bhatnagar
National Professional Officer - Deputy Team Lead (NPSP)
SE_IND WR Office, India

Responsible Divisional Director
Directeur de division responsable

Pem NAMGYAL
Director, Programme Management
SE/DPM Director, Programme Management

Authorized Signatory:
Signataire autorisé:

Mr Motohiro Ogita
Coordinator
Global Procurement and Logistics
(WHO/GMG/GSC/GPL)

Motohiro Ogita
Coordinator
HQ/GSC Global Service Centre
15-JUN-2018

PRINCIPAL INVESTIGATOR/ *CHERCHEUR PRINCIPAL*

Principal Investigator or Technical Officer responsible for the project.
Chercheur Principal ou membre du personnel technique responsable de l'exécution du projet.

Signature : .....
DR.Jeetendra Gavhane

ON BEHALF OF THE INSTITUTION/ *POUR L'INSTITUTION*

Responsible Administrative Authority*
*Autorité administrative responsable**

Signature : .....
Name/*nom* : .....
Division : .....
Date : .....

* An official of the Institution - other than the Principal Investigator - fully empowered to enter into contracting arrangements on behalf of the Institution./*Un responsable de l'Institution autre que le Chercheur principal - ayant pleins pouvoirs pour passer un contrat au nom de l'Institution.*

Global Procurement and Logistics
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Reference	2018/820923-0
Purchase Order	202016253
Unit Reference	Polio/WR-India

TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

GENERAL CONDITIONS

The following are the general conditions relating to this Agreement concerning WHO support for research or other technical services. The purpose of such support is to assist an Institution to undertake, for WHO, investigations on a particular problem or other work which has been agreed upon by the Institution and WHO.

1 INSTITUTION AND PRINCIPAL INVESTIGATOR

1.1 The Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee of the Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in this Agreement.

1.2 The Institution is required to notify WHO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities covered by this Agreement. Under such circumstances WHO has the right to:

a. cancel this Agreement or

b. agree to continue the project under a new Principal Investigator proposed by the Institution and approved by WHO.

2. FINANCIAL ARRANGEMENTS

2.1 Payments shall be made to the bank account(s) of the Institution as specified in this Agreement and in accordance with the schedule of payments contained therein. If, after the submission of the final financial report referred to in paragraph 4.3 below, there remains an unused balance of funds with the Institution, this balance shall be due to WHO. In the event of this Agreement being cancelled under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds. The funds provided under this Agreement shall be spent only in accordance with its terms.

2.2 The funds transferred to the Institution under this Agreement may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to a staff member of WHO.

2.3 Unless otherwise provided in this Agreement the funds may not be used to cover:

a. normal administrative and overhead expenses of the Institution;

b. cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution;

c. cost of construction of new buildings or alterations and modifications of existing buildings and premises;

d. salary support of the Principal Investigator.

3. EQUIPMENT AND SUPPLIES

3.1 Unless otherwise agreed, and subject to subparagraph 3.2 below, any equipment acquired under this Agreement shall become the property of the Institution. The Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment acquired under this Agreement.

3.2 Notwithstanding subparagraph 3.1 above, the Institution shall transfer ownership of any equipment acquired under this Agreement to WHO, if so requested by WHO, upon termination or expiry of this Agreement. In such cases the Institution shall dispatch the equipment to any destination chosen by WHO, the cost of which will be borne by WHO.

4. REPORTS

The Institution shall submit technical and financial reports to WHO on the work as required, or at least annually, in accordance with the following provisions:

4.1 Technical reports shall be prepared by the Principal Investigator and forwarded through and countersigned by the authorized official of the Institution or his authorized representative. Each annual report shall summarize the results of the project and give in sufficient detail its positive and negative findings so that the value of the work can be assessed.

4.2 Financial reports shall be forwarded after being jointly certified by the Institution's Chief Financial Officer and the Principal Investigator, using form WHO 782. The reports must show the use of the funds provided by WHO compared with the original budget expenditure pattern agreed between the Institution and WHO.

4.3 All Financial and Technical reports are subject to audit by WHO, including examination of supporting documentation and relevant accounting entries in the Institution's books. In order to facilitate such reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project. The final Technical and Financial reports must be submitted within 90 days after the expiry of this Agreement.

5. RELATIONSHIP AND RESPONSIBILITY OF PARTIES

The relationship of the Institution to WHO shall be that of an independent contractor. The employees of the Institution are not entitled to describe themselves as staff members of WHO. The Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement. No liability shall attach to WHO, its advisers, agents or employees.

6. USE OF RESULTS, EXPLOITATION OF RIGHTS, AND PUBLICATION

6.1 The results of the project funded under this Agreement may be freely used or disclosed by either party provided that, without the consent of the other party, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by proprietary rights. The Institution shall provide WHO with the results, in the form of relevant know how and other information, and to the extent feasible, tangible products.

6.2 The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:

a. the general availability of the products of creative activity;

b. the availability of those products to the public health sector on preferential terms, particularly in developing countries;

c. the grant to each party of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the research.

6.3 The rights referred to in para. 6.2 shall belong to the Institution, or to the Principal Investigator if the Institution and WHO so agree. To the extent that the former do not intend to exercise them, the rights shall be promptly transferred to WHO, if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of the rights. The party in which the corresponding rights are vested may file applications for industrial property protection, promptly furnishing copies of the applications and other patent documents to the other party. All rights other than the right to file applications shall be exercised in accordance with an agreement which shall be negotiated in good faith between the Institution and WHO.

6.4 In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO. Unless WHO advises otherwise, all publications shall include a notice indicating that the underlying investigation received financial support from WHO. Two off-prints or copies shall be sent to WHO unless another number is stipulated. WHO funds may not be used for publication costs unless specifically authorized.

7. RESEARCH INVOLVING HUMAN SUBJECTS

7.1 Ethical Aspects

It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from WHO, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Such funds may be used only to support investigations where (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and (d) any special national requirements have been met.

7.2 Regulatory Requirements

It is the responsibility of the Institution and the Principal Investigator to comply with the relevant national regulations pertaining to research involving human subjects.

7.3 Protection of Subjects

Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 7.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and Principal Investigator undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this Agreement.

8. RESEARCH INVOLVING THE USE OF LABORATORY ANIMALS

The Institution undertakes that living vertebrate animals, required for use as laboratory animals for the research to be carried out under this Agreement, shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

9. RESEARCH SAFETY

It is the responsibility of the Institution to establish and implement policies and practices to assure and provide for the safety of its employees, the public, and the environment during the conduct of the supported research. If the supported research involves the use of dangerous biological agents, the Institution shall establish and implement an appropriate safety plan.

10. PUBLICITY

The Institution and the Principal Investigator shall not refer to the relationship of WHO to the project, or to products or processes connected with the project, in any statement or material of a publicity or promotional nature issued for commercial purposes, or with a view to financial benefit.

11. SETTLEMENT OF DISPUTES

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

12. PRIVILEGES AND IMMUNITIES

Nothing contained in or relating to this Agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

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Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

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TECHNICAL SERVICES AGREEMENT
ACCORD DE SERVICES TECHNIQUES

CONDITIONS GENERALES

Les conditions générales énoncées ci-après s'appliquent au présent Accord sur l'appui de l'OMS aux recherches ou autres services techniques. Cet appui vise à aider une institution à entreprendre pour le compte de l'OMS, des investigations portant sur un problème particulier ou des travaux convenus entre l'Institution et l'OMS.

1. INSTITUTION ET CHERCHEUR PRINCIPAL

1.1 L'Institution et le Chercheur principal (ou l'Administrateur technique responsable), lequel doit être employé par l'Institution, sont conjointement responsables de l'ensemble des aspects techniques et administratifs des travaux visés par le présent Accord.

1.2 L'Institution est tenue d'aviser immédiatement l'OMS lorsqu'elle apprend que le Chercheur principal va cesser, ou a cessé, d'être employé par elle, ou bien qu'il ne continue pas à exercer les fonctions visées par le présent Accord. En pareil cas, l'OMS peut:

a. soit annuler le présent Accord;

b. soit accepter de poursuivre le projet sous la conduite d'un nouveau Chercheur principal proposé par l'Institution et approuvé par l'OMS.

2. DISPOSITIONS FINANCIERES

2.1 Des versements seront faits au(x) compte(s) bancaire(s) de l'Institution comme il est stipulé dans le présent Accord et conformément au calendrier qui y figure. Si, après communication du rapport financier final mentionné plus loin au paragraphe 4.3, il apparait que l'Institution détient un solde non utilisé, ce solde reste payable à l'OMS. En cas d'annulation du présent Accord, quelles qu'en soient les circonstances, l'Institution restituera à l'OMS les sommes non encore engagées. Les sommes fournies en vertu du présent Accord ne pourront être dépensées que conformément aux dispositions dudit Accord.

2.2 Les fonds versés à l'Institution en vertu du présent Accord ne peuvent être utilisés pour verser des émoluments quelconques à un fonctionnaire de l'OMS, couvrir ses frais de voyage ou lui rembourser toute autre dépense.

2.3 Sauf dispositions contraires du présent Accord, ces fonds ne peuvent être utilisés pour couvrir:

a. les dépenses administratives et les frais généraux normaux de l'Institution;

b. le coût de l'entretien, de la réparation, de l'exploitation ou de l'assurance de matériels ou d'appareils existants qui appartiennent à l'Institution;

c. le coût de la construction de nouveaux bâtiments, ou de la transformation ou de la modification de bâtiments et locaux existants;

d. le versement d'un complément de traitement au Chercheur principal.

3. MATERIEL ET FOURNITURES

3.1 Sauf convention contraire, et sous réserve des dispositions de l'alinéa 3.2 ci-après, tout matériel obtenu en vertu du présent Accord sera la propriété de l'Institution. L'Institution et le Chercheur principal seront conjointement responsables du bon état de conservation et d'entretien de tout matériel acquis en application du présent Accord.

3.2 Nonobstant les dispositions de l'alinéa 3.1 ci-dessus et si l'OMS en fait la demande, l'Institution transférera à celle-ci, lors de la résiliation ou de l'expiration du présent Accord les droits de propriété afférents à tout matériel acquis au titre dudit Accord. L'Institution expédiera alors ce matériel vers toute destination que lui aura indiquée l'OMS, les frais d'expédition étant à la charge de cette dernière.

4. RAPPORTS

L'Institution soumettra à l'OMS des rapports techniques et financiers concernant ses travaux, chaque fois qu'il y a lieu et au moins une fois par an, selon les modalités suivantes.

4.1 Les rapports techniques seront établis par le Chercheur principal, envoyés sous couvert du responsable de l'Institution ou de son représentant l'un et l' autre dûment autorisés, et contresignés par eux. Chaque rapport annuel résumera les résultats du projet et en exposera les conclusions positives ou négatives de façon assez détaillée pour permettre d'apprécier la valeur des travaux.

4.2 Les rapports financiers devront être envoyés, après avoir été visés conjointement par le Chef des Services financiers de l'Institution et par le Chercheur principal qui utiliseront à cette fin la formule WHO 782. Les rapports devront indiquer l'utilisation des fonds provenant de l'OMS au regard des prévisions de dépenses initiales dont étaient convenues l'Institution et l'OMS.

4.3 Tous les rapports financiers et techniques sont soumis par l'OMS à une vérification comprenant l'examen de toutes pièces justificatives ainsi que des écritures comptables correspondantes dans les livres de l'Institution. En vue de faciliter l' établissement et la vérification de ces rapports, l'Institution veillera à la tenue de comptes et de registres exacts et systématiques pour tout ce qui concerne le projet. Les rapports techniques et financiers finaux devront être présentés dans les 90 jours suivant l'expiration du présent Accord.

5. RELATIONS ENTRE LES PARTIES ET LEURS RESPONSABILITES

L'Institution agira à l'égard de l'OMS en tant qu'entrepreneur indépendant; ses employés ne pourront se prévaloir de la qualité de membres du personnel de l'OMS. L'Institution sera seule responsable de la façon dont s'exécute le projet et, partant, assumera l' entière responsabilité de tout dommage résultant de recherches ou d'autres services techniques visés par le présent Accord. Aucune responsabilité ne pourra incomber à l'OMS, ses conseillers, agents ou employés.

6. UTILISATION DES RESULTATS, EXPLOITATION DES DROITS, ET PUBLICATION

6.1 Les résultats du projet financé en vertu du présent Accord pourront être librement utilisés ou divulgués par l'une ou l'autre partie. Toutefois, à défaut de l'assentiment de l'autre partie, les résultats ne pourront être utilisés à des fins commerciales et, s'ils sont susceptibles d'être protégés par des droits de propriété, ils conserveront leur caractère strictement confidentiel. L'Institution communiquera à l'OMS les résultats des recherches, sous forme de savoir-faire et autres intellectuelle, y compris les droits qui s'attachent au savoir-faire, découlant du projet, devra permettre, dans toute la mesure du possible, d'atteindre les objectifs suivants énoncés par ordre de priorité:

a. mise à la disposition de tous les produits de l' activité créatrice;

b. leur mise à la disposition du secteur de la santé publique, notamment dans les pays en développement à des conditions préférentielles;

c. octroi à chaque partie d'avantages additionnels, y compris sous formes de redevances, compte tenu de la valeur relative de ses contributions financières, intellectuelles et autres.

6.3 Les droits mentionnés plus haut au paragraphe 6.2 seront la propriété de l'Institution, ou du Chercheur principal si l'Institution et l'OMS en conviennent ainsi. Dans la mesure où l'Institution n'entend pas les exercer, les droits seront promptement transmis à l'OMS, si celle-ci le demande. Chaque partie coopérera pleinement avec l'autre pour lui permettre d'exercer effectivement ses droits. La partie détentrice des droits pourra déposer des demandes de propriété industrielle et devra alors remettre à l' autre partie copie de ces dépôts et des autres documents relatifs au brevet. Tous les droits autres que celui de déposer des demandes s'exercent aux termes d'un accord qui sera négocié de bonne foi entre l'Institution et l'OMS.

6.4 Dans aucune de ses publications concernant les résultats du projet, l'Institution ou le Chercheur principal n'attribuera à l'OMS la responsabilité de la direction des travaux. Sauf instructions contraires de l'OMS, toutes les publications comporteront une note indiquant que les recherches qui sont à l'origine des résultats ont reçu un appui financier de l'OMS. A moins qu'un autre chiffre n'ait été stipulé, deux exemplaires ou tirés à part de ces publications seront envoyés à l'OMS et, sauf autorisation expresse, les fonds de l'OMS ne pourront être utilisés pour couvrir les coûts de publication.

7. RECHERCHES IMPLIQUANT L'ETUDE DE SUJETS HUMAINS.

7.1 Aspects déontologiques

Il incombe à l'Institution et au Chercheur principal de s'assurer qu'au cours des travaux financés totalement ou en partie par l'OMS et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code de déontologie ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Les fonds ne peuvent être utilisés pour financer des recherches que si les conditions suivantes sont remplies:

a. les droits et le bien-être des sujets impliqués sont suffisamment protégés;

b. le consentement libre et éclairé des intéressés a été obtenu;

c. des experts indépendants désignés par l'Institution ont pesé les risques et les avantages potentiels et ont jugé qu'ils s'équilibraient de manière acceptable; et

d. il ait satisfait à toute exigence particulière de la réglementation nationale.

7.2 Dispositions réglementaires

Il incombe à l'Institution et au Chercheur principal de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.

7.3 Protection des sujets d'expérience

Sans préjudice des obligations qui lui incombent aux termes des lois en vigueur, l'Institution prendra des mesures appropriées en vue d'éliminer ou d'atténuer les conséquences des expériences pour les sujets ou leur famille en cas de décès, de traumatisme ou de maladie résultant de la conduite des recherches mentionnées au paragraphe 7.1. Ces mesures comprendront, dans la mesure du possible, un traitement médical et un dédommagement financier. L'Institution et le Chercheur principal s'engagent à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études effectuées en vertu du présent Accord.

8. RECHERCHES IMPLIQUANT L'UTILISATION D'ANIMAUX DE LABORATOIRE

L'Institution s'engage à veiller à ce que les animaux vertébrés vivants qu'il sera nécessaire d'utiliser comme animaux de laboratoire pour des recherches entreprises en vertu du présent Accord soient traités conformément aux principes universellement reconnus qui veulent que l'on épargne à ces animaux toute souffrance inutile.

9. SECURITE DES RECHERCHES

Il incombe à l'Institution d'arrêter et d'appliquer des politiques et pratiques préservant et garantissant la sécurité de ses employés et du public ainsi que celle de l' environnement pendant les recherches soutenues par l'OMS. Si les travaux impliquent l'utilisation de substances biologiques dangereuses, l'Institution établira et appliquera un plan de sécurité approprié.

10. PUBLICITE

L'Institution et le Chercheur principal ne pourront faire mention, dans un quelconque écrit ou déclaration à caractère publicitaire ou promotionnel diffusé à des fins commerciales, ou en vue d'un avantage financier, du lien existant entre l'OMS et le projet ou les produits ou procédés en découlant.

11. REGLEMENT DES LITIGES

Toute question concernant l'application ou l'interprétation du présent Accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent Accord qui n'aurait pu être résolu à l' amiable, fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en absence d'accord, seront déterminées selon le règlement d'arbitrage de la Chambre de Commerce Internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

12. PRIVILÈGES ET IMMUNITÉS

Aucun des termes du présent Accord ne sera considéré comme constituant une

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD, U.P- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311
e-mail: pvpi@ipcindia.net, ipclab@ysnl.net, Web: www.ipc.gov.in

File no.: IPC/NCC-PvPI/AMCs/2017-18/102 **Date: 06/06/2017**

To,

Dr. Abhijeet Bhagat,
Assistant Professor,
Department of Pharmacology,
Mahatma Gandhi Mission (MGM),
N-6, Cidco,
Aurangabad,
Maharashtra-431003

Sub: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI.

Sir/Madam,

This is with reference to your letter of intent to participate in nationwide programme to monitor the safety of drugs, it is a matter of great pleasure to bring in your kind notice that the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) - **Pharmacovigilance Programme of India (PvPI)**, Ghaziabad has agreed in principle to recognise your institution as an Adverse Drug Reactions Monitoring Centre under PvPI.

The detailed roles and responsibilities and resource materials will be sent to you after your acceptance.

Please accept our heartiest congratulations.

With regards

Yours faithfully

(Dr. G. N. Singh)
Secretary-cum-Scientific Director

Copy to:

a) The Dean, Mahatma Gandhi Mission (MGM), Aurangabad, Maharashtra
b) The Administrative Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh
c) The Finance & Accounts Officer, Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh

DIRECTORATE OF HEALTH SERVICES.
(MAHARASHTRA STATE)

Arogya Bhavan, St.George's Hospital Compound, P.D'Mello Road, Mumbai-400 001.

	Tel.No.	Website : http://maha-arogya.gov.in Email : adhsthoa@gmail.com Fax No. 022-22621034 / 22620234 (DHS) 022-22679044 (Hosp.) 022-22703861(THOA)
Office: Director(Personal) Jt.Director(Hospital) ADHS (THOA)	22621031-36 22621006 22611471 22703861	
		NO.DHS/THOA/MGM med College & Hosp,A'bad./Corneal TranpTeam/19. Date- 23 /04/2019

To,
Dean,
MGM Medical College & Hospital,
N-6, Cidco, Aurangbad-431003,.

Sub:- **Transplantation of Human Organ Act 1994 & Amendment 2011**
Cornea Transplant Team

Ref:- Your application did. 15/01/2019

With reference to your application, the **Cornea Transplant Team** of specialists whose names have been sent to this office for the approval of the State Appropriate Authority under the provision of the Transplantation of Human Organs Act 1994, for the purpose of Cornea Transplantations operations in your hospital, the State Appropriate Authority herewith grants recognition to the **Cornea Transplant Team** of your hospital as shown as below. **This is valid for the period of five years from the date of issue.**

CORNEA TRANSPLANT TEAM

Sr.No.	Designation	Name of Consultant
1	**Transplant Surgeon**	Dr. Sarika Gadekar, Ophthalmologist
2	**Transplant Anesthesiologist**	Dr. Vasanti Kelkar, Anesthesiologist Dr. Ajita Annachatre (Dunk), Anesthesiologist Dr. Anuradha Jogdand, Anesthesiologist

- If any doctor resigns the institute, then intimate immediately to the Appropriate Authority.
- If any new doctor is joining to your institute, then before joining the team, the institute has to take the permission on behalf of the doctor from Appropriate Authority, without which the newly joined doctor cannot work in the transplantation program.

Dr. Anupkumar Yadav
Commissioner (Health & Family welfare)
and
Director Health Services, Mumbai

MGM's Medical College Aurangabad

DIRECTORATE OF HEALTH SERVICES,
(MAHARASHTRA STATE)

Arogya Bhavan, St.George's Hospital Compound, P.D'Mello Road, Mumbai-400 001.

	Tel.No.	Website : http://maha-arogya.gov.in
Office:	22621031-36	Email : adhsthoa@gmail.com
Director(Personal)	22621006	Fax No. 022-22621034 / 22620234 (DHS)
Jt.Director(Hospital)	22611471	022-22679044 (Hosp.)
ADHS (THOA)	22703861	022-22703861(THOA)

No.DHS/THOA/ MGM med.College & Hosp.A'bad./ /Corneal Transp./Reg/D-20/19

Date- 23 /04/2019

To,
Dean,
MGM Medical College & Hospital,
N-6, Cidco, Aurangbad-431003.

Sub:- **Transplantation of Human Organ Act 1994 & Amendment 2011**
Cornea Transplant Registration

Ref:- Your application dtd. 15/01/2019

With reference to your application, please find enclosed herewith the approval for following Committee.

1) Certificate of Registration for Cornea Transplantation.
2) Approval for following committees
   a) Cornea Transplant Team

You are instructed to affiliate your hospital with District Blindness Control Society & with Director Regional Organ & Tissue Transplant Organization (ROTTO) Mumbai & Director, National Organ & Tissue Transplant Organization (NOTTO) New Delhi for co-ordination of deceased (cadaver) donor organ transplant activities.

You should regularly submit monthly performance report in the prescribed format.

You are instructed to follow all the provisions in the Transplantation of Human Organs Act 1994 & Rules 1995, Transplantation of Human Organs (Amendment) Rules, 2008 and Transplantation of Human Organs (Amendments) Act, 2011 & Rules 2014.

Please acknowledge the same.

Dr. Anupkumar Yadav
Commissioner (Health & Family welfare)
and
Director Health Services, Mumbai

C.C.to: 1) Joint Director Health Services (NPCB) Mumbai.
2) Secretary, Regional Organ & Tissue Transplant Organization K.E.M. Hospital Parel Mumbai.
3) Director, National Organ & Tissue Transplant Organisation, 4th & 5th Floor, NIOP Bldg., Safdarjung Hospital, New Delhi-110029.

Government of Maharashtra

FORM 16

CERTIFICATE OF REGISTRATION FOR PERFORMING ORGAN/TISSUE TRANSPLANTATION/RETRIEVAL AND OR TISSUE BANKING

[Refer Rule No. 24(2)]

This is to certify that MAHATMA GANDHI MISSION MEDICAL COLLEGE & HOSPITAL Hospital/Tissue Bank located at N-6, CIDCO, AURANGABAD-431003 has been inspected and certificate of registration is granted for performing the organ/tissue retrieval/Transplantation/Banking of the following organ(s)/tissue(s) (mention the names) under the Transplantation of Human Organ Act, 1994(42 of 1994):-

1. CORNEA TRANSPLANT CENTRE

This certificate is valid for a period of five years from the date issue.

This permission is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and /or facility must be brought to the notice of the undersigned.

संचालक आरोग्य सेवा, महाराष्ट्र राज्य, मुंबई

Place:- Mumbai

Date :- 23/04/2019

Signature of Appropriate Authority

समुचित प्रधिकरण

Seal.....

तथा

संचालक आरोग्य सेवा,
महाराष्ट्र राज्य, मुंबई

MGM's Medical College

Dr. Shroff's Charity Eye Hospital
Caring for the community since 1914...

2018/022

Dr. Shroff's Charity Eye Hospital, Delhi

hereby certifies that

Dr. Sarika Gadekar

has successfully completed short-term fellowship in Cornea
&
Hands-on Penetrating Keratoplasty Surgery

from September to November 2018

Dr. Umang Mathur
Executive Director

Dr. Abha Gaur
Incharge - Cornea Fellowship

Dr. Suma Ganesh
Head – Medical Education Dept.

5027, Kedarnath Road, Daryaganj, New Delhi-110002, India Ph. No. 011-43524444 / 43528888

DIRECTORATE OF HEALTH SERVICES.
(MAHARASHTRA STATE)
Arogya Bhavan, St.George's Hospital Compound, P.D'Mello Road, Mumbai-400 001.

आरोग्य सेवा संचालनालय
(महाराष्ट्र राज्य)
आरोग्य भवन सेंट जॉर्जेस रुग्णालय आवार, पी.डिमेलो रोड, मुंबई- ४०० ००१

	दूरध्वनी	
कार्यालय	२२६२१०३१-३६	Website : http://maha-arogya.gov.in
संचालक (वैयक्तिक)	२२६२१००६	Email : adhsthoa@gmail.com
सहसंचालक (रुग्णालये-राज्यस्तर)	२२६११४७१	Email : jdhs03@gmail.com
सहा.संचालक (माअप्र)	२२७०३८६१	Fax No. 022-22621034 / 22620234 (DHS)
		022- 22679044(Hosp.)
		022-22703861 (THAO)
रजिस्टर ए.डी.		क्र.संआसे/माअप्र//एमजीएममेडिकलकॉलेज औरंगाबाद/ईडीसी/नोंदणी/कक्ष-२०/१५
		दिनांक:- ०५/०८/२०१५

प्रति,
अधिष्ठाता एमजीएम मेडिकल
कॉलेज ॲन्ड हॉस्पीटल,
एन-६,सीडको, औरंगाबाद.

विषय - मानवी अवयव प्रत्यारोपण कायदा १९९४ अंतर्गत आयडोनेशन सेंटर म्हणून नोंदणी मिळणेबाबत.
संदर्भ - आपला प्रस्ताव दि. ६.१०.२०१४

उपरोक्त संदर्भिय विषयाच्या अनुषंगाने आपणास कळविण्यात येते की, आपण मागणी केल्यानुसार आपल्या रुग्णालयास आयडोनेशन सेंटर म्हणून नोंदणी नुतणीकरण प्रमाणपत्र देण्यात येत आहे. सदर प्रमाणपत्राची वैधता प्रमाणपत्र दिल्याच्या दिनांकापासून पुढील पाच वर्षासाठी राहील. नोंदणी प्रमाणपत्राच्या तारखेच्या ३ महिने अगोदर नूतणीकरणचा प्रस्ताव या संचालनालयास सादर करणे आवश्यक राहील याची नोंद घ्यावी.

सोबतः प्रमाणपत्र

5/8/15
समुचित प्राधिकरण तथा
संचालक आरोग्य सेवा
महाराष्ट्र राज्य मुंबई

प्रतः सहसंचालक आरोग्य सेवा (अंनिका) मुंबई यांना माहितीसाठी.

9-10-2015
3.40 PM.

Date of Issue - 5/8/2015
Date of Expiry Renewal - 5/8/2020
Date of Renewal - 5/4/2020.

Government of Maharashtra

सत्यमेव जयते
महाराष्ट्र शासन

Office of the Appropriate Authority

Certificate of Registration

No. DHS/ THOA/MGM MED COLL/ EDC /F.No /D-20/2015

This is to certify that MAHATMA GANDHI MISSION, MEDICAL COLLEGE & Hospital located at CIDCO, AURANGABAD has been inspected by the Appropriate Authority and certificate of registration is granted for performing the organ transplantation of the following organs:-

1. EYE DONATION CENTER
2. _____
3. _____
4. _____

This certificate of registration is valid for a period of five years from the date of issue .

Mumbai:

Date: 05/08/2015

संचालक आरोग्य सेवा, महाराष्ट्र राज्य, मुंबई

Appropriate Authority
and
Director Health Services,
Maharashtra State, Mumbai
सक्षम प्राधिकरण
तथा
संचालक आरोग्य सेवा,
महाराष्ट्र राज्य, मुंबई

DIRECTORATE OF HEALTH SERVICES.
(MAHARASHTRA STATE)
Arogya Bhavan, St.George's Hospital Compound, P.D'Mello Road, Mumbai-400 001.

आरोग्य सेवा संचालनालय
(महाराष्ट्र राज्य)

" आरोग्य भवन ", सेंट जॉर्जेस रुग्णालय आवार, पी.डिमेलो रोड, मुंबई- ४०० ००१

कार्यालय	दूरध्वनी	Website : http://maha-arogya.gov.in Email : dhs_2005@rediffmail.com Email : miscell@rediffmail.com Fax No. 022-22621034 / 22620234 (DHS) 022- 22679044(Hosp.) 022-22622155(CAO) 022-22703785(Control Room) 022-22621047 (NCD)
संचालक (वैयक्तिक)	२२६२१०३१-३६	
सहसंचालक (रुग्णालये-राज्यस्तर)	२२६२१००६	
सहसंचालक (प्राआकेंद्र-जिपस्तर)	२२६११४७१	
सहसंचालक (असंसर्गजन्य रोग)	२२६२०२४९	
सहसंचालक (खरेदी कक्ष)	२२६२११८६	
सहसंचालक (अर्थ व आस्थापना)	२२६२६२८२	
	२२६२६७५५	

क्र.संआसे/डायलेसीस/ प्रशिक्षण/कक्ष ३/२०१३
दिनांक - ४/०४/२०१३

प्रति,

१) विभाग प्रमुख,
नेफ्रॉलॉजी डिपार्टमेंट,
के.ई.एम. हॉस्पीटल मुंबई, बी.जे.एल.नायर रुग्णालय, जे.जे समूह रुग्णालय, बी.जे. वैद्यकिय महाविद्यालय पुणे, के.ई.एम रुग्णालय पुणे, सुपर स्पेशालिटी हॉस्पीटल नागपूर, (अंतर्गत जी.एम.सी.नागपूर), जी.एम.सी औरंगाबाद, एम.जी.एम औरंगाबाद, मिरज मेडिकल कॉलेज मिरज, वैद्यकिय अधिक्षक सुपर स्पेशालिटी हॉस्पीटल अमरावती व नाशिक

विषय:- राज्यातील जिल्हा रुग्णालये मधे सुरु करण्यात येणाऱ्या डायलेसीस युनिट मधील भिषक/वैद्यकिय अधिकारी /स्टॉफ नर्सेस/ डायलीसीस टेक्नीशियन यांना प्रशिक्षण देणेबाबत...

संदर्भ:- मा. संचालक डी.एम.ई.आर यांचे पत्र क्र.संवैशिवस/संआसे/डायलेसीस/ तंत्रज्ञ/ प्रशिक्षण/४-३ दि.१५/२/२०१३.

उपरोक्त संदर्भाधिन विषयाव्दारे आपणास कळविण्यात येते की, राज्यातील सर्व जिल्हा रुग्णालये/ सामान्य रुग्णालये व उपजिल्हा रुग्णालय शेगांव व पंढरपूर/ नांदेड स्त्री रुग्णालय या ठिकाणी लवकरच डायलेसीस युनिटस सुरु करण्यात येणार आहेत. तत्पूर्वी या युनिट मधे कार्यरत होणाऱ्या सर्वांचे गुणवत्तापूर्ण प्रशिक्षण होणे गरजेचे आहे. या प्रशिक्षणाचा आराखडा ठरविणे तसेच प्रशिक्षणामध्ये समन्वयाच्या दृष्टीने नेफ्रॉलॉजी युनिट प्रमुख संबंधित हॉस्पीटलस यांची बैठक दिनांक १६/४/२०१३ रोजी दुपारी ३ वाजता आरोग्य सेवा संचालनालय, मुंबई (आठवा मजला,

[नि.प्र.ध.अ./मुं.सा.वि./३ग.

No. 4401

सत्यमेव जयते

नोंदणी प्रमाणपत्र

याद्वारे प्रमाणपत्र देण्यात येते की, खाली वर्णन केलेली सार्वजनिक विश्वस्तव्यवस्था ही आज, मुंबई सार्वजनिक विश्वस्तव्यवस्था अधिनियम, १९५० (सन १९५० चा मुंबई अधिनियम २९) या अन्वये Aurangabad Region, Aurangabad. येथील सार्वजनिक विश्वस्तव्यवस्था नोंदणी कार्यालयात योग्य रितीने नोंदण्यात आलेली आहे.

सार्वजनिक विश्वस्तव्यवस्थेचे नाव : Zonal Transplantation Coordination Centee, Aurangabad.

सार्वजनिक विश्वस्तव्यवस्थांच्या नोंदणी पुस्तकातील क्रमांक : E - 1298 (A.bad)

Dr. Sudhir Gajanan Kulkarni यांस प्रमाणपत्र दिले.

आज दिनांक 12.04.2016 २०१- रोजी माझ्या सहीनिशी दिले.

शिक्का : Assistant Charity Commissioner, Aurangabad Region, Aurangabad

सही 12/4/16

पदनाम

WOM's Medical Centre, Aurangabad

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy.Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/Desk-RNTCP/TB/ 6967-52 /17
Date 2/4/2017

To,
The Dean,
Mahtma Gandhi Mission
Medical College Aurangabad

Sub:- Sanction of grant-in-aid for the Thesis proposal under RNTCP.

Ref:- The State Operational Research Committee meeting held on 17th February, 2017 at Disha Hall, Parivartan Building, Arogya Bhavan, Pune.

The following thesis proposal submitted by the Principal Investigator (PI) of your institute was discussed in State Operational Research Committee Meeting held on 17th February, 2017 under RNTCP and it has been approved.

Sr. no	Name of the PI	Name of the Department & Medical College	Topic
1	Dr. Prashant D. Warkari, PG Student	Department of community medicine, MGM Medical College, Aurangabad	Management of tuberculosis patients according to RNTCP by private practitioners in Aurangabad City - A cross sectional study.

The Principal Investigator (PI) will sign a Memorandum of Undertaking (MOU) with the TB programme manager on behalf of the society for the release of funds. The MOU will include the objects for which he will utilize the funds and the timeline for the study. It will also include the commitment from him to return the funds if the study cannot be taken up due to any reason, and other relevant causes. Funds will be released on the name of the institution of the Principal Investigator, so that the College / Department can ensure the study of its completion / return the funds in the event that the Principal Investigator is moved from the college during the course of the study. A Grant-in-aid of **Rs. 30,000 (Rs. Thirty Thousand only)** for the above thesis proposal will be released from the "Medical College Budget Head" from RNTCP funds by City TB Officer, Aurnagabad. 80% of the grant-in-aid will be released initially and remaining 20% after receiving the report i.e. receipt of the four hardcopies of the Thesis.

Joint Director of Health Services
(Leprosy & TB) Pune

Copy to –
1. The CTO Aurangabad– To follow up with the respective medical college & PG student and release the grant-in-aid amount of Rs. 30,000 (Rs. Thirty Thousand only) from the "Medical College Budget Head" from RNTCP funds as per the guidelines.

2. The Principal Investigator –
   Dr. Prashant D. Warkari, PG Student, Department of community medicine, MGM Medical College, Aurangabad

3. The RNTCP Medical Consultants by email – mhconsultants@rntcp.org

4. The OR Committee Members ..... (All)

Copy with complements to –
Dr. Babaji Ghewade, Professor Respirator Medicine, Chief Medical Superintendent, Acharya Vinoba Bhave Rural Hospital and Jawaharlal Nehru Medical College, Wardha &
Chairman State OR Committee, Maharashtra

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy.Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/ Desk- RNTCP/TB/ 7405-10 /18
Date 19/5/2018

To,
The Dean,
Mahatma Gandhi Mission Medical College,
Navi Mumbai

Sub:- Sanction of grant-in-aid for the Operational Research proposal under RNTCP.

Ref:- The State Operational Research Committee meeting held on 26th September, 2017 at Disha Hall, Parivartan Building, Arogya Bhavan, Pune.

The following Operational Research proposal submitted by the Principal Investigator (PI) of your institute was discussed in State Operational Research Committee Meeting held on 26th September, 2017 under RNTCP and it has been approved.

Sr. no	Name of the PI	Name of the Department & Medical College	Topic
1	Dr. P. V. Potdar, Principal Investigator	Department of Respiratory, MGM Hospital, Navi Mumbai	Study, evaluate and analysis of MGM - TB detector system

The Principal Investigator (PI) will sign a Memorandum of Undertaking (MOU) with the TB programme manager on behalf of the society for the release of funds. The MOU will include the objects for which he will utilize the funds and the timeline for the study. It will also include the commitment from him to return the funds if the study cannot be taken up due to any reason, and other relevant causes. Funds will be released on the name of the institution of the Principal Investigator, so that the College / Department can ensure the study of its completion / return the funds in the event that the Principal Investigator is moved from the college during the course of the study.

A Grant-in-aid of **Rs. 2,00,000 (Rs. Two lac only)** for the above OR proposal will be released from the "Medical College Budget Head" from RNTCP funds by City TB Officer, Navi Mumbai Municipal Corporation 50% of the grant-in-aid will be released initially and remaining 30%

after receiving the report of data analysis and 20% will be released after receipt of the four hardcopies of the final documents.

Joint Director of Health Services
(Leprosy & TB) Pune

Copy to –

1. The CTO Navi Mumbai– To follow up with the respective medical college & Principal Investigator and release the grant-in-aid amount of Rs. 2,00,000 (Rs. Two lac only) from the "Medical College Budget Head" from RNTCP funds as per the guidelines.

2. Dr. P. V. Potdar, Principal Investigator, Department of Respiratory, MGM Hospital, Navi Mumbai

3. The RNTCP Medical Consultants by email – mhconsultants@rntcp.org

4. The OR Committee Members ..... (All)

Copy with complements to –

Dr. Babaji Ghewade, Chairman State OR Committee, Maharashtra & Professor Respirator Medicine, Chief Medical Superintendent, Acharya Vinoba Bhave Rural Hospital and Jawaharlal Nehru Medical College, Wardha

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Ref: SBS/18/4/544
Date: 25/4/18

दूरभाष/TEL : 26962819, 26567373
(EPABX) : 26565694, 26562133
: 26565687, 26562144
: 26562134, 26562122
फैक्स/FAX : 26960629, 26529745
Website : http:/www.dsir.gov.in
(आईएसओ 9001:2008 प्रमाणित विभाग)
(AN ISO 9001:2008 CERTIFIED DEPARTMENT)

सूचना का अधिकार
RIGHT TO INFORMATION

सत्यमेव जयते

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
वैज्ञानिक और औद्योगिक अनुसंधान विभाग
टेक्नोलॉजी भवन, नया महरौली मार्ग,
नई दिल्ली - 110016
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
Department of Scientific and Industrial Research
Technology Bhavan, New Mehrauli Road,
New Delhi - 110016

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

F.No. 14/596/2011-TU V

Date: 04 April, 2018

The Dean
Mahatma Gandhi Misson's Medical College
Plot No. 1 & 2, Sector-18, Kamothe,,
Navi Mumbai -410 209
Maharashtra

Subject : **Renewal of Recognition of Scientific and Industrial Research Organisations (SIROs).**

Dear Sir,

This has reference to your application for renewal of recognition of Mahatma Gandhi Misson's Medical College, Navi Mumbai, Maharashtra as a Scientific and Industrial Research Organisation (SIRO) by the Department of Scientific and Industrial Research under the Scheme on Recognition of Scientific and Industrial Research Organisations (SIROs), 1988.

2. This is to inform you that it has been decided to accord renewal of recognition to **Mahatma Gandhi Misson's Medical College, Navi Mumbai, Maharashtra from 01.04.2018 upto 31.03.2021.** The recognition is subject to terms and conditions mentioned overleaf.

3. Receipt of this letter may kindly be acknowledged.

MGM SCHOOL OF BIOMEDICAL SCIENCES
Inward No. MGM/SBS/ 740
Date 24/4/18
Receiver Signature

M... ED
Inward No. 2542
Date 20/4/18
SIGN :

Yours faithfully,

Deshpande
(Dr. S.K. Deshpande)
Scientist - 'G'

Cc to Med. Supdt
cc to M4(?)0(?)
cc to Research Unit
to MS
Send copy to DY

File and forwarded to Poonam
24/04/2018

American Heart Association.
life is why

International Training Agreement

Company Information:

International Training Center ("ITC"):	Mahatma Gandhi Mission Medical College
Address:	MGM Medical College, Plot 1 and 2, Sector 1, Kamothe, Navi Mumbai, Maharashtra 410209
Form of Organization:	Not for Profit / Medical College

This Agreement is between the American Heart Association, Inc. ("AHA"), a New York not-for-profit corporation, having its principal offices at 7272 Greenville Avenue, Dallas, Texas 75231-4596, and ITC.

IN CONSIDERATION of the mutual promises contained herein, the parties agree as follows:

1. Term: Beginning Date: November 21, 2017. Ending Date: November 21, 2019. This Agreement will be in effect for a period of Two (2) calendar years. It may be renewed for additional one (1) year periods by letter issued from AHA.

2. AHA ECC Courses to be Taught by ITC:

Basic Life Support	Advanced Cardiac Life Support
Provider Course(s)	Provider Course(s)
Instructor Course(s)	Instructor Course(s)

3. Geographic Territory: India

4. Insurance: $30,750.36 (US$)

ITC will obtain and maintain at its expense, commencing upon the beginning date of this Agreement and during its entire term, liability insurance from a qualified insurance carrier, as set out above. This policy will specify that it may not be modified or canceled by the insurer, except after thirty (30) days prior written notice by the insurer. Upon execution of this Agreement ITC will provide the AHA with a certificate of insurance showing the required coverage.

5. Copyrights: ITC acknowledges and agrees that the AHA owns all copyrights in the ECC Materials, and ITC may not copy, or permit others to copy, distribute, perform or make derivative works based upon the ECC Materials, Course Completion Cards, or eCards.

6. Marks: ITC acknowledges the AHA's trademark rights and ownership of the name "American Heart Association", the heart-and-torch trademark and slogans (e.g., "Life is Why") (hereinafter "AHA Marks"). ITC will not use or display the AHA Marks. ITC shall not apply for any trademark registrations with respect to any AHA Marks or any marks similar to the AHA Marks.

7. Entire Agreement: This Agreement, including the terms and conditions set out on Page Two, contains the entire agreement between the parties relating to the rights granted and the obligations assumed.

EXECUTED by the parties on the date(s) set out below.

American Heart Association, Inc.	**International Training Center**
Signature:	Signature:
Name: Michael Herbert	Name: DR. G.S. Narshetty
Title: Director, International Operations	Title: Dean
Date: 11/21/17	Date: 12/28/2017

M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

American Heart Association | American Stroke Association
life is why

New Training Center Information

Purpose:

This memo provides you with your security code for purchasing course completion cards, your TC ID # to use to correspond with the AHA on questions about your training center as well as information about how to obtain the exams, and how to access the Instructor Network and CPRverify website.

TC Code:

ECC International welcome's you to the American Heart Association's Training Network.

As part of your training center process you should become familiar with the Program Administration Manual. There is an international version of the PAM located on CPRverify. You can access the PAM by logging into CPRverify, click on the information tab and in keyword field type PAM.

We hope this helps you in your daily operations of your training center. Should you have any questions please feel free to contact me via email at pamela.rojas@heart.org.

Included in this email is your TC ID #. Your TC ID # is a number that is assigned to you by us so that we can identify your training center when you submit training reports, survey's etc.

Your TC ID # is: ZZ21290

Please do not confuse this number with your security code listed below.

Security Code and Purchasing Course Cards:

Your security code is used to purchase course completion cards from the distributor. Your security code is issued only to you, as the ITC Coordinator you are responsible for all course completion cards that are issued by your training center and training sites that report to you. Please do not give this code to anyone.

Your security code is: C99208A8

For a list of Authorized International Distributors please visit the AHA International Heart website.

When purchasing course completion cards please provide the following information to the distributor:

Legal Name of ITC – this is the name on your training center agreement.

Training Center Coordinator Name

Security Code

If someone is ordering course completion cards for your organization or company they must use the information provided above. They would place the order and state "as authorized by" and give the name of your training center. This will prevent delays in your order being processed and shipped.

Please let me know if you have any questions about ordering cards from the Distributors.

CPRverify:

As a new training center with AHA you will receive information regarding the CPRverify program. CPRverify makes it easier for our international training centers to track and monitor their training sites, instructors and students. CPRverify is the International Training Center's resource for all course and ITC related materials, such as:

- Course Exams
- Skills Testing Checklist
- Translated Course Resources
- Program Administration Manual (PAM)
- Training Memo and Communications from the AHA

Exams:

Much time and effort has gone into the development of AHA cognitive tests. These exams are developed and reviewed by both educational and science experts for their discipline. Security and integrity of exams must be maintained at all times.

Please remember all exams are copyright protected and should not be altered or translated. If specific translations are needed you must submit a copyright permission request via our website.

Your training center is responsible for developing a security policy for AHA exams. Exams should only be given to Course Directors authorized for the discipline being taught.

The American Heart Association's exams are to be kept confidential, maintaining security is of the utmost importance

The individual appointed as the Training Center Coordinator, will be able to access the exams on CPRverify under the "Exams" tab.

Please email cprverify@heart.org, if you have any questions or are unable to access your exams.

Instructor Network:

The Instructor Network is available as an option for international training centers. Much of the information located on the Instructor Network is now in CPRverify. You and your instructors may benefit from the use of the Instructor Community located on the Instructor Network.

The system will send you an email to create your profile. You will receive an email from our system that looks like this:

American Heart Association.
life is why

PLEASE DO NOT REPLY TO THIS EMAIL ADDRESS. YOU WILL NOT RECEIVE A RESPONSE TO REPLIES TO THIS EMAIL ADDRESS.

Dear ,

As a Training Center Coordinator (TCC), you have been approved for automatic access to the American Heart Association Instructor Network. A TCC account has now been created for you with the site. Through your special "TCC only" view of the AHA Instructor Network, you will be able to:

- Access the "Training Centers" area to receive targeted content and tools available only to TCCs
- Maintain Instructor Lists and Course Completions
- Pre-approve Instructors and HSSEs for access to the AHA Instructor Network (NOTE: full access is not available until Instructors/HSSEs also register with the Network)
- Confirm Instructors and HSSE for access to the AHA Instructor Network
- Deny and/or deactivate Instructors or HSSEs
- Send bulk or individual emails directly from the AHA Instructor Network (using your own email system)
- And MUCH MORE!

Please visit the AHA Instructor Network to complete your Training Center Coordinator Account

Note: If for some reason the above link does not work, please copy and paste this URL into your web browser:

https://ahainstructornetwork.americanheart.org/registration/common/completeProfile.jsp?application=eccportal&action=editProfile&id=ZWNjMTE1NzA5MjQ=

Thank you for all you do to provide lifesaving training!

Sincerely,
AHA Instructor Network

If you do not receive the email above within five days of receiving this welcome email please let me know at pamela.rojas@heart.org. Please note: you may want to check your spam/junk folder, to make sure it is not there.

Your username will be your email address and for password, you need to enter the password at the time of completing the profile when you click on the link from the email.

Thank you,
Pamela Rojas
American Heart Association International
Data Specialist

Government of India
Department of Atomic Energy
BRNS Secretariat

Central Complex, 1st floor
BARC, Mumbai 400 085

No. 2012/36/15-BRNS/

Date: 25-7-2012

Office Memorandum

Sub: R/P entitled "Development of micro biosensor for rapid diagnosis of tuberculosis (TB)" under Dr. D.S. Joshi, MGM College of Engineering and Technology, Sector 18, Kamothe, Navi Mumbai 410 209

On the recommendations of the Board of Research in Nuclear Sciences (BRNS), I am directed to convey the administrative approval and sanction of the President of India for the captioned project for two years beginning from financial year 2012-13 with a total grant of Rs.23,82,750/- as detailed below:

	Item of expenditure	I year (2012-13)	II year (2013-14)
*	Equipment	Rs.12,00,000	--
	Consumable	Rs. 4,00,000	Rs.1,35,000
	Travel : PI	Rs. 1,25,000	Rs.1,25,000
	Contingency	Rs. 50,000	Rs. 50,000
&	Overhead	Rs. 1,29,375	Rs. 19,500
		Rs.19,04,375	Rs.3,29,500

* (1) Biosafety cabinet level II/III, (2) Deep freezer, (3) Photomultiplier with fiber optics adaptors, (4) Laser light source with filter tubes, (4) Lyophilizer

& Overhead calculated @ 7.5% of other heads **except** contingency. The remaining 7.5% towards overhead (Rs.1,48,875) shall be released only on meeting the requirements specified (**see Annex-B**).

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

Government of India
Department of Atomic Energy
BRNS Secretariat

Central Complex, 1st floor
BARC, Mumbai 400 085

No. 2012/36/14-BRNS/ 1165-7

Date: 22 MAY 2013

Sub: R/P entitled "Development of photonic crystal waveguide (PCW) based multiplexers for optical networks and sensor applications" under Dr. S.K. Narayankhedkar, Principal, MGM College of Engineering and Technology, Sector 18, Kamothe, Navi Mumbai 410 209

This is in continuation of BRNS letter No. 2012/36/14-BRNS/ - dated 25.7.2012. Approval of BRNS is conveyed for the inclusion of the following in the project.

1.	Principal Investigator	Dr. S.K. Narayankhedkar
		Principal, MGM College of Engineering and Technology
		Sector 18, Kamothe, Navi Mumbai 410 209
2.	Co-Principal Investigator	Dr. Raman Yadav
		MGM Institute of Health Sciences
		Sector 18, Kamothe, Navi Mumbai 410 209
3.	Principal Collaborator	Dr. V.K. Suri
		Head, PED, BARC, Mumbai 400 085
4.	Co-Principal Collaborator(1)	Dr. R. Balasubramaniam
		PED, BARC, Mumbai 400 085
5.	Co-Principal Collaborator(2)	Dr. Shivam Mishra
		PED, BARC, Mumbai 400 085

The other terms and conditions of Office Memorandum No. 2012/36/14-BRNS/ - dated 25.7.2012. will remain unchanged.

(Dr. Debanik Roy)
Programme Officer, BRNS

Dr. S.K. Narayankhedkar
Principal, MGM College of Engineering and Technology
Sector 18, Kamothe, Navi Mumbai 410 209

Copy to :

1. Member Secretary, NRFCC : Dr. Vivekanand Kain, Materials Science Division, BARC, Trombay, Mumbai-400 085
2. Member Secretary, TSC-3, NRFCC : Dr. Kallol Roy, RRMD, BARC, Mumbai-85
3. Principal Collaborator : Dr. V.K. Suri, Head, PED, BARC, Mumbai 400 085
4. Co-Principal Collaborator (1) : Dr. R. Balsubramaniam, PED, BARC, Mumbai-85
5. Co-Principal Collaborator (2) : Shri M. Shivam Mishra PED, BARC, Mumbai-85
6. Co-Principal Investigator : Dr. Raman Yadav, MGM Institute of Health Sciences, Sector 18, Kamothe, Navi Mumbai 410 209

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai-410 209

Please Distribute to the Addressee as Marked(✓)

Government of India
Department of Atomic Energy (DAE)
Board of Research in Nuclear Sciences (BRNS)

Shri D. K. Dalal
Programme Officer (ATC)

BRNS Secretariat, 1st Floor, CC,
BARC, Trombay, Mumbai-400085
Phone: 25594683 FAX: 022-25505151
E-mail: dkdalal@barc.gov.in

No. 34/14/57/2014-BRNS/ 2126

Date: 17 DEC 2014

OFFICE MEMORANDUM

Sub: R/P entitled "Non-Invasive Monitoring of Heamoglobin and Blood Sugar" under Dr. G. D. Jindal, Head, Department of Biomedical Engineering, MGM College of Engineering & Technology, Kamothe, Navi Mumbai 410 209 bearing sanction **No.34/14/57/2014-BRNS** with **ATC**, BRNS.

On the recommendations of the Board of Research in Nuclear Sciences (BRNS), I am pleased to convey the administrative approval and sanction of the President of India for the captioned project for two years beginning from financial year **2014-15** with a total grant of **₹23,44,100/- (Rupees twenty three lakh forty four thousand one hundred only)** for the project as under:

	Item of expenditure	I Year (2014-2015)	II Year (2015-2016)
*	Equipment	11,18,000	--
#	Staff JRF (1)	1,92,000	1,92,000
	Consumables	1,50,000	1,50,000
	Travel (PI)	35,000	35,000
	Contingency	60,000	60,000
$	Overheads	1,16,775	28,275
	Total:	17,33,775	4,65,275
		16,71,775	

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC)
Navi Mumbai-410 209

(i) Battery operated Oscilloscope, (ii) Spectro-photometer, (iii) Personal Computer with standard accessories and printer, (iv) Camera.

JRF salary is calculated @ ₹16,000/- per month.

$ Overheads calculated @ 7.5% of the other heads except contingency. The remaining 7.5% towards overheads (**₹1,45,050/-**) shall be released only on meeting the requirements specified.

2. I am also pleased to convey the sanction of the President of India to incur an expenditure of **₹17,33,775/- (Rupees seventeen lakh thirty three thousand seven hundred seventy five only)** towards grant for the year **2014-15**.

3. The expenditure involved is debitable to:

Grant No.	-	04	Atomic Energy
Major Head	-	3401	Atomic Energy Research
Minor Head	-	00 004	Research & Development
Sub Head	-	08 02	Board of Research in Nuclear Sciences (BRNS)
Detailed Head	-	08 02 31	Grant-in-aid

4. This issues with the concurrence of Scientific Secretary, BRNS and IFA, DAE.

Sd/-
(D. K. Dalal)

Pay & Accounts Officer,
Department of Atomic Energy,
Anushakti Bhavan,
CSM Marg, Mumbai - 400 001.

No. 34/14/57/2014-BRNS/ Date:

Copy forwarded to:

1. Director of Audit, Scientific Department, AEAP, OYC, CSM Marg, Mumbai - 400 001.
2. Joint Secretary (R&D), DAE, Anushakti Bhavan, CSM Marg, Mumbai-400 001.
3. Principal, MGM College of Engineering & Technology, Kamothe, Navi Mumbai 410 209.
4. ** Principal Investigator (PI): Dr. G. D. Jindal, Head, Department of Biomedical Engineering, MGM College of Engineering & Technology, Kamothe, Navi Mumbai 410 209.

A. First year grant is being released in full through Pay & Accounts Officer, Department of Atomic Energy, Anushakti Bhavan, CSM Marg, Mumbai-400 001 directly into your institute's account by ECS.

i) Receipt of this sanction letter and the DD/ MT for the amount sanctioned for the first financial year may please be acknowledged **(Form-I)**.

ii) THIS SANCTION IS FURTHER SUBJECT TO THE TERMS AND CONDITIONS FOR RESEARCH PROJECTS **(ENCLOSED)**, WHICH MAY BE GONE THROUGH CAREFULLY.

B. Second year Sanction Letter will be issued automatically in the month of April/May of the 2nd financial year, however, the grant will be released after the PI submits the following documents to the Programme Officer, BRNS:

a) Claim in Form-II **(enclosed)** quoting the reference of the sanction issued for the first year.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in Form-III **(enclosed)** duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in Form-IV **(enclosed)** duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant. **Interest earned in previous year should be reflected in the Statement of Accounts.**

d) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

e) An inventory of equipment in Form-V **(enclosed)**.

f) A One Page reports on the progress of work during first year.

C. Grant for the third year and subsequent years (if any), will be released only after the Principal Investigator (PI) fulfills the following requirement:

i) The Department will issue a fresh sanction for the third and subsequent years after receiving the recommendation of the BRNS after scrutiny of the Renewal Application in Form PRA.

Hence, Principal Investigator (PI) is required to submit a renewal/extension application in the prescribed **Form - PRA** by email to Member Secretary (ATC) (**snjha@barc.gov.in**) by **January 1** of the second and subsequent years of the project as the case may be alongwith the progress report giving year wise details of the progress made. Form-PRA is also available on www.daebrns.gov.in A printed copy of the application duly signed and forwarded by head of the institution should also be submitted to the Member Secretary (ATC) as well as Programme Officer (ATC), BRNS, 1st Floor, Central Complex, BARC, Mumbai-400 085 by **January 15**.

ii) Sanction Letter: If the progress is found to be satisfactory the renewal sanction for the year will be issued in the beginning of that financial year in April/May.

iii) Claim: On receipt of the renewal sanction, the PI shall claim the funds sanctioned by submitting the following documents to **Shri D. K. Dalal, Programme Officer (ATC), BRNS Secretariat, First Floor, Central Complex, BARC, Trombay, Mumbai-400 085**:

a) Claim in **Form-II** (enclosed) quoting reference of the renewal sanction.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in **Form-III** (enclosed) duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in **Form-IV** (enclosed) duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant. **Interest earned in previous year should be reflected in the Statement of Accounts.**

d) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

e) An inventory of equipment **in Form-V** (enclosed).

These forms are enclosed with the sanction letter (first year) also.

D. At the end of Terminal Year the final Settlement Grant will be released on fulfillment of the following requirements:

a) Claim Form-II,

b) The final Consolidated Statement of Accounts (SA) and Consolidated Utilization Certificate (UC) **duly audited by a Chartered Accountant or a Statutory (Govt.) Auditor.**

c) Final Consolidated Progress Report **in Form-VII** (enclosed).

5. AAO (Bills II), DAE, Anushakti Bhavan, CSM Marg, Mumbai - 400 001 – With a request that amount granted for the first year of the project may be released immediately.

6. Member Secretary (ATC): Dr. S. N. Jha, Room No.4, INDUS-2 Building, RRCAT, Indore 452013.

7. Co-Investigator (CI): Dr. Sandhya Agarwal, Head, Bio-Tech Department, MGM College of Engineering & Technology, Kamothe, Navi Mumbai 410 209.

8. Principal Collaborator (PC): Dr. Rajesh Kumar Jain, ED, BARC, Mumbai 400 085.

You or your nominee may please be the DAE representative for selection of Research Fellow/ Research Associate for the project.

(D. K. Dalal)

** **Note:**

1. All the documents as applicable be sent in time to avoid delays and unnecessary correspondence.
2. Please quote Sanction No. **34/14/57/2014-BRNS** in all your correspondence with BRNS.
3. If you do not receive the money please contact AAO (Bills II), DAE **on 022-22862711.**

सत्यमेव जयते

Government of India
Department of Atomic Energy (DAE)
Board of Research in Nuclear Sciences (BRNS)

Shri D. K. Dalal
Programme Officer (ATC)

BRNS Secretariat, 1st Floor, CC,
BARC, Trombay, Mumbai-400085
Phone: 25594683 FAX: 022-25505151
e-mail: dkdalal@barc.gov.in

No. 34/14/08/2014-BRNS/ 34084

Date: 23/3/16

OFFICE MEMORANDUM

Sub: Terminal grant-in-aid for the year 2015-16 for R/P entitled "Confirmation of Nano-Particle Hypothesis with Respect to Homeopathic Medicines" under Dr. Mansee Rathore, Asst. Professor in Biotechnology, MGM Institute of Health Sciences, Sector-18, Kamothe, Navi Mumbai 410 209 bearing sanction No.34/14/08/2014-BRNS with ATC, BRNS.

In continuation of this Department's Office Memorandum no. 34/14/08/2014-BRNS/0136 dated 23/04/2014, on the recommendations of Board of Research in Nuclear Sciences (BRNS), I am pleased to convey the administrative approval of the President of India for the continuance of captioned project during **2015-16** and sanction to incur an expenditure of **Rs. 6,09,250/- (Rupees six lakh nine thousand two hundred and fifty only)** as detailed below:-

	Item of expenditure	II Year (2015-2016)
#	Staff JRF (1)	3,00,000
	Technical Assistance	50,000
	Consumables	1,00,000
	Travel (PI)	20,000
	Contingency	50,000
$	Overheads	35,250
*	Staff Salary Arrears	54,000
	Total	**6,09,250**

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, '56)
Navi Mumbai-410 209

MGM / MED
INWARD NO. 2161
DATE 2/4/16
SIGN :

JRF Fellowship is calculated @ Rs.25, 000/- p.m.

$ Overheads calculated @ 7.5% of the other heads **except** contingency. The remaining 7.5% towards overheads (₹ 35,250/-) shall be released only on meeting the requirements specified.

* Staff Salary arrears is calculated w.e.f. 01/10/2014.

2. **The captioned project will stand terminated on 31/3/2016.**

1) Cheque PI

Cert MGMIHS.

3. The expenditure involved is debitable to:

Grant No.	-	04	Atomic Energy
Major Head	-	3401	Atomic Energy Research
Minor Head	-	00 004	Research & Development
Sub Head	-	08 02	Board of Research in Nuclear Sciences (BRNS)
Detailed Head	-	08 02 31	Grant-in-aid

4. This issues with the concurrence Scientific Secretary, BRNS and IFA.

Sd/-
(D. K. Dalal)

Pay & Accounts Officer,
Department of Atomic Energy,
Anushakti Bhavan,
CSM Marg, Mumbai - 400 001.

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai-410 209

Copy forwarded to:

1. Director of Audit, Scientific Department, AEAP, OYC, CSM Marg, Mumbai - 400 001.
2. Joint Secretary (R&D), DAE, Anushakti Bhavan, CSM Marg, Mumbai-400 001.
3. Dean, MGM Medical College & Hospital, Kamothe, Navi Mumbai 410 209.
4. ** Principal Investigator (PI): Dr. Mansee Rathore, Asst. Professor in Biotechnology, MGM Institute of Health Sciences, Sector-18, Kamothe, Navi Mumbai 410 209.

A. In accordance with Rule 30 of the General Financial Rules, 2005 this sanction will lapse if no payment in whole or part is made during a period of twelve months from the date of issue of this sanction letter.

B. Grant for the terminal year will be released in FULL (unspent balance of previous year and interest earned on unutilized grant will be adjusted) on receipt of the following documents:

(a) Claim form (Form. II) **in duplicate**
(b) Utilisation Certificate (FORM-III) – for the preceding years ***as on 31.03.2015*** signed by Internal Auditor / Accountant of the Institution / University.
(c) Statement of Accounts (FORM-IV) for the preceding years ***as on 31.03.2015*** signed by Internal Auditor / Accountant of the Institution / University. **Interest earned should be reflected in the Statement of Accounts.**
(d) Copy of appointment order and joining report of the staff appointed for the project alongwith Minutes of the Selection Committee.
(e) An Inventory of equipment (FORM-V).
(f) Detailed Progress Report of previous year.

C. **PLEASE NOTE THAT CLAIM/S SHALL BE SUBMITTED TO THIS DEPARTMENT WELL IN ADVANCE BEFORE THE END OF THE FINANCIAL YEAR IN WHICH THE CLAIM IS DUE. OTHERWISE, THE SANCTIONED GRANT WILL LAPSE.**

D. The balance 7.5% of 'Overhead' grant shall be released after completion of the project on receipt of the following documents:

(1) **Final Claim form** (FORM II) **in Duplicate**
(2) Consolidated AUDITED Statement of Accounts from a Statutory Auditor (Govt. Auditor) or a Chartered Accountant for the grant-in-aid paid during the previous years (Form-IV). (***See Annex –B***)
(3) Utilisation Certificate from a Statutory Auditor (Govt. Auditor) or a Chartered Accountant to the effect that grant received during the years were utilized for the purpose for which they were sanctioned (Form-III).
(4) An Inventory of Equipment (Form-V) and
(5) A Final Consolidated Project Report (5 copies).

E. Final claim in support of the items listed in para **4(D) (1 to 4)** may be submitted alongwith **5 copies** of the consolidated Report of the project within **3 months** from the date of termination of the project. If the claims are not received within the stipulated period, it will be presumed that the Investigator has no further claim, and the file will be closed.

F. The grant remaining unutilized, if any, may be refunded vide DD drawn in favour of **"Pay & Accounts Officer, DAE, Mumbai"** and sent to BRNS Secretariat along with documents listed at Para (D) above. The unutilized grant may be refunded in whole rupees by rounding off the amount to the nearest rupee.

G. Attention is also invited to the procedure regarding publication of papers (vide Para 7 of the Annexure to the "Terms and Conditions" already sent to you along with first year sanction letter), the above has been classified as 'Unreserve' for the purpose of the publication of results of the work.

5. AAO (Bills-II), DAE Anushakti Bhavan, CSM Marg, Mumbai - 400 001.

6. Member Secretary, ATC : Dr. S. N. Jha, Room no 4, Indus -2 Building, Raja Rammana Centre for Advanced Technology (RRCAT), Indore 452013.

7. Co-Investigator (CI): Dr. Alka Deshpande, Director, Internal Medicine, MGM Institute of Health Sciences, Sector-18, Kamothe, Navi Mumbai 410 209.

(D. K. Dalal)

** **Note:**
1. All documents as applicable be sent in time to avoid delays & unnecessary correspondence.
2. Please quote Sanction No. **34/14/08/2014-BRNS** in all your correspondence with BRNS.

Government of India
Department of Atomic Energy
BRNS Secretariat

Central Complex, 1st floor
BARC, Mumbai 400 085

No.36(2)/14/26/2014-BRNS/ 1367

Date: 18 AUG 2014

Office Memorandum

Sub: R/P entitled "Development of prototype micro-PCR device for identification of MDR MTB" under Dr. Mansee Thakur, M.G.M. Institute of Health Sciences, Secator 18, Kamothe, Navi Mumbai 410 209

On the recommendations of the Board of Research in Nuclear Sciences (BRNS), I am directed to convey the administrative approval and sanction of the President of India for the captioned project for two years beginning from financial year 2014-15 with a total grant of Rs.24,98,900/- (Rupees twenty four lakh ninety eight thousand nine hundred only) as detailed below:

	Item of expenditure	I year	II year
		(2014-15)	(2015-16)
#	Staff : JRF(1)	Rs. 1,92,000	Rs. 1,92,000
$	Technical Assistance	Rs. 96,000	Rs. 96,000
	Consumable	Rs. 8,00,000	Rs. 6,10,000
	Travel : PI	Rs. 50,000	Rs. 50,000
	Contingency	Rs. 50,000	Rs. 50,000
&	Overhead	Rs. 85,350	Rs. 71,100
	Total	**Rs.12,73,350**	**Rs.10,69,100**

JRF fellowship calculated @ Rs.16,000/- per month for two years.

$ Technical Assistance includes equipment hire charges, computer charges and charges for hiring services.

& Overhead calculated @ 7.5% of other heads **except** contingency. The remaining 7.5% towards overhead (Rs.1,56,450) shall be released only on meeting the requirements specified (**see Annex-B**).

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

2. I am also directed to convey the sanction of the President of India to incur an expenditure of Rs.12,73,350/- (Rupees twelve lakh seventy three thousand three hundred fifty only) towards grant for the financial year 2014-15.

3. The expenditure involved is debitable to :

Grant No.	:	04	- Atomic Energy
Major Head	:	3401	- Atomic Energy Research
Minor Head	:	00 004	- Research & Development
Sub head	:	08 02	- BRNS
Detailed Head	:	08 02 31	- Grant-in-Aid

4. This issues with the concurrence of Scientific Secretary, BRNS and IFA.

Sd
(Dr. Debanik Roy)
Programme Officer, BRNS

Pay and Accounts Officer
Department of Atomic Energy
CSM Marg
Mumbai 400 001

No.36(2)/14/26/2014-BRNS/ Date :

Copy forwarded to:

1. Director of Audit, Scientific Department, AEAP, OYC, CSM Marg, Mumbai - 400 001.
2. Joint Secretary (R&D), DAE, Anushakti Bhavan, CSM Marg, Mumbai-400 001.
3. Director, M.G.M. Institute of Health Sciences, Sector 18, Kamothe, Navi Mumbai 410 209
4. ** Principal Investigator : Dr. Mansee Thakur, M.G.M. Institute of Health Sciences, Sector 18, Kamothe, Navi Mumbai 410 209

A. First year grant is being released in full vide ECS through Pay & Accounts Officer, Department of Atomic Energy, Anushakti Bhavan, CSM Marg, Mumbai-400 001 directly.

i) **Receipt of this sanction letter and grant for the amount sanctioned for the first financial year may please be acknowledged** (Form-I).

ii) THIS SANCTION IS FURTHER SUBJECT TO THE CONDITIONS STIPULATED IN ANNEX-A, ANNEX-B AND ANNEX-C **(ENCLOSED)**, WHICH MAY BE GONE THROUGH CAREFULLY.

B. Second year grant will be released after the PI submits the following documents to the Programme Officer (NRFCC):

a) Claim in Form-II **(enclosed)** quoting the reference of the sanction issued for the first year.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in Form-III **(enclosed)** showing bank interest accrued and duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in Form-IV **(enclosed)** showing bank interest accrued and duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

d) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

e) An inventory of equipment in Form-V **(enclosed)**.

f) A One Page report on the progress of work during first year.

C. Grant for the third year and subsequent years (if any), will be released only after the Principal Investigator (PI) fulfills the following requirement:

i) The Department will issue a fresh sanction for the third and subsequent years after receiving the recommendations of the BRNS after scrutiny of the Renewal Application in Form 4R.

Hence, **2 copies** of renewal request in the **Form 4R (enclosed)** and **2 copies** of detailed Progress Report must reach to **Dr. Vivekanand Kain, (MS, NRFCC), Materials Science Division, BARC, Mumbai-400 085** and one copy of **Form 4R** to **Dr. Debanik Roy, Programme Officer (NRFCC), BRNS Secretariat, First Floor, Central Complex, BARC, Trombay, Mumbai-400 085** on or before **30th November of the second or subsequent year of the project as the case may be**.

ii) If the progress is found to be satisfactory the renewal sanction for the year will be issued in the beginning of that financial year.

iii) On receipt of the renewal sanction, the PI shall claim the funds sanctioned by submitting the following documents to **Programme Officer (NRFCC)**:

a) Claim in Form II **(enclosed)** quoting reference of the renewal sanction.

b) Utilisation Certificate (UC) as on **31st March** of the preceding financial year in Form-III **(enclosed)** showing bank interest accrued and duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

c) Statement of Accounts (SA) as on **31st March** of the preceding financial year in Form-IV **(enclosed)** showing bank interest accrued and duly audited by the Internal Auditor of the University/ Institution or a Chartered Accountant.

d) However, the final consolidated Statement of Accounts/ Utilization Certificate showing bank interest accrued to be submitted at the end of the Terminal year shall be audited by a Chartered Accountant or the Statutory (Govt.) Auditor

e) Copy of appointment order and joining report of the staff appointed for the project along with minutes of the Selection Committee.

f) An inventory of equipment in Form-V **(enclosed)**.

g) Final consolidated Progress Report for settling the Terminal Grant.

5. AAO (Bills II), DAE, Anushakti Bhavan, CSM Marg, Mumbai - 400 001 – With a request that the amount granted for the first year of the project may be released immediately.

6. Member Secretary, NRFCC : Dr. V. Kain, MSD, BARC, Mumbai-400 085

7. Member Secretary, TSC-2, NRFCC : Shri V. Bhasin, RSD, Hall-7, BARC, Mumba-85

8. Principal Collaborator : Dr. V.K. Suri, Head, PED, BARC, Mumbai 400 085 - You or your nominee may please be the DAE representative for selection of Research Fellow / Research Associate for the project.

9. Co-Principal Investigator (1) : Dr. D.S. Joshi, M.G.M. Institute of Health Sciences, Sector 18, Kamothe, Navi Mumbai 410 209

10. Co-Principal Investigator (2) : Dr. Sudhir Kadam, M.G.M. Institute of Health Sciences, Sectpr 18, Kamothe, Navi Mumbai 410 209

Debanik Roy

(Dr. Debanik Roy)
Programme Officer, BRNS

** Note : Please quote the Sanction Number (**No.36(2)/14/26/2014-BRNS)** in all your correspondence with BRNS.

Annexure - I

Detailed Project Activities

Details of the activities to be undertaken by University Department of Physiotherapy, MGM Institute of Health Sciences, Sector No1, Plot No 1 & 2, Kamothe, Navi Mumbai 410209 under the project entitled **"Development of Powered Transtibial Prosthesis".**

Please find enclosed a detailed copy of the project proposal submitted to DBT for reference. Refer to pages 21 & 22.

Objectives:

1. Gait analysis of adults with transtibial amputation

Annexure – II

Details of Funds

PI's NAME AND ADDRESS

Dr. Rajani P Mullerpatan, University Department of Physiotherapy, MGM Institute of Health Sciences, Sector No1, Plot No 1 & 2, Kamothe, Navi Mumbai:410209

Items	*I year*	*II year*	*III year*	Total
Non-recurring	22500 USD x68.58 INR= 1543,050=00			1543,050=00
Manpower	480,000	480,000	480,000	1440000=00
Consumables				50000=00
Travel				As per DBT norms
Contingencies				
Overhead				
Total				**3033,050=00**

MGM INSTITUTE OF HEALTH SCIENCES Deemed University Navi Mumbai

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

Annexure - I

Detailed Project Activities

Details of the activities to be undertaken by University Department of Physiotherapy, MGM Institute of Health Sciences, Sector No1, Plot No 1 & 2, Kamothe, Navi Mumbai 410209 under the project entitled **"Development of Powered Transtibial Prosthesis".**

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Annexure – II

Details of Funds

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Dr. Rajani P Mullerpatan, University Department of Physiotherapy, MGM Institute of Health Sciences, Sector No1, Plot No 1 & 2, Kamothe, Navi Mumbai:410209

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Travel				As per DBT norms
Contingencies				
Overhead				
Total				**3033,050=00**

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029 Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.Indo-US/83/9/2010-ECD-II

Dated: 24/11/14

To

The Director
MGM Medical College and Hospital,
Kamothe, Navi Mumbai-410209.

Subject: Termination of the enquiry entitled, "SHAKTI : Stigma reduction Health care provider awareness and Knowledge enhancement on Transgender issues in India" under Dr.H.R.Jerajani

Sir,

As you are aware, the Council has been providing financial assistance in respect of the above mentioned enquiry which is being carried out at your Institution.

As the duration of the project, the work of the enquiry is due to terminate with effect from **28.02.2014(a.n.)** no member of staff will have to be retained after that date. The staff employed on the enquiry may be informed in writing that their services will not be required beyond the planned duration of the study.

A list (in duplicate) of non-expendable articles and of available expendable articles purchased for work of the enquiry together with the property register should be sent to the Council with suggestion as regards to their disposal.

An audit certificate from the auditors to the effect that the accounts have been audited and the money was actually spent on the object, for which it was sanctioned, may be sent to the Council. In case it is likely to take some time in getting the accounts audited by the authorized auditors of the Institute, a statement of account in respect of the grant available in termination of the enquiry should be refunded to the Council by means of a bank draft or cheques made out n the name of the Director-General, ICMR. The draft or cheque should be sent under registered cover.

A final report of work done on the enquiry since its inception duly prepared in the format given overleaf may please be sent **(15 copies) to the Council within two week from the date of receipt of the termination letter of the enquiry**.

Contd...

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

- Maintain all the research related documents in a confidential manner
- Identify and recruit the field research staff for the project
- Periodically update MGM about all project activities and outcomes
- Maintain financial records for all project related expenses
- Safe guard data collection instruments such as survey questionnaire, consent forms, submit quarterly financial reports (raising quarterly invoice and quarterly statement of expenditure)

4. **Financial support for implementing the project activities (March 1, 2012 to February 28, 2013)**
   - The overall cost for implementing the project activities through HST is estimated to be **1241744/-** , this includes staffing, admin and research related costs. Given below is the breakup for your reference

   I. **Research staff**
   - Senior Technical Assistant at HST (Non-Medical) @ 26183 = 26183 x 12. Overall cost: **314196**
     Field worker at HST @ 17546 x 12. Overall cost: **210552**
   - Data entry operator (grade A) @ 15462 x 12. Overall cost: **185544**
   - Data Entry operator (grad B) @17546 x 12. Overall cost: **210552**

   II. **Contingency/ recurring**
   - Compensation to

   1. Participants 64 x 350 x 8FGD=22400
   2.10 interviews x350=3500
   Overall cost: **25900**
   - Training and translation of research documents (interview guides, consent forms, FGD and KII guides) at HST overall cost: **15000**
   - Workshop to evaluate formative data and design the intervention .at HST overall cost: 60000

   III. **Communication**
   - High speed internet at HST @ 2000 x 12. Overall cost: **24000**
   - Phone bill, fax at HST @ 1000 x 12. Overall cost: **12000**

   IV. **Stationery And Photocopying at HST = 10000**

   V. **Community advisory board meeting.=30000**

   VI. **Travel**
   Local travel at HST @ Overall cost at HST: **25000**

   VII. **Equipment**
   -Laptop at MGM = **50000**

   VIII. **Digital voice recorder** 12000 X 2=**24000**

   IX. NVIO 9 software for qualitative data analyses (multiple user license) = **45000**

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2015 ◑ NA 438353

- 9 OCT 2015

पुरवठाधारीदीक
उपकोषागाराचे नांव-पनवेल,
जि. रायगड

उपकोषागार अधिकारी
पनवेल - रायगड.

AGREEMENT

By and between

Maaya Foundation
(hereinafter called "MF")
#117, 13th Main Road, Sector 5, HSR Layout, Bangalore - 560102
Karnataka State (India)

and

MGM Institute of Health Sciences
(Deemed University under Section 3 of UGC Act, 1956)
(Hereinafter called 'MGM Institute')
MGM Educational Campus, Sector 1, Kamothe,
Navi Mumbai – 410 209, Maharashtra State (India)

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Concerned

The Care of Children with Craniofacial Deformities and Cleft Lip and Palate

MGM INSTITUTE OF HEALTH SCIENCES
Deemed University NAVI MUMBAI

Received 2 sets from Mukesh Chawla
18/11/15

दस्त प्रकार / अनुच्छेद क्रमांक Nature of Document	Agreement
दस्त नोंदणी करणार आहात का ? Whether it is to Register?	—
नोंदणी होणार असल्यास दुय्यम निबंधक कार्यालयाचे नाव (If Registrable Name of S.R.O.)	Kamothe
मिळकतीचे वर्णन (Property description in brief)	—
मोबदला रक्कम (Consideration Amount)	—
मुद्रांक विकत घेणाऱ्याचे नांव (Stamp Purchaser Name)	M.G.M. Institute of Health science
दुसऱ्या पक्षकाराचे नांव (Name of other Party)	maaya foundation
हस्ते असल्यास त्यांचे नाव व पत्ता (Through other person then Name & Add.)	sushant shinde
मुद्रांक शुल्क रक्कम (Stamp duty amount)	100/-
मुद्रांक विक्री नोंद वही अनुक्रमांक / दिनांक (Serial No. / Date)	12029
मुद्रांक विकत घेणाऱ्याची सही (Stamp Purchaser Sign.)	Shinde

सौ. धनश्री सुरेश कोंद्रे
मुद्रांक परवाना क्र. ७/१९९६-९७
ऑफिस नं.१, साईधारा कॉम्प्लेक्स, पहिला मजला,
सेक्टर-८, खांदा कॉलनी, नवीन पनवेल (प)

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे

dtd 17/11/2016

RECITALS

A. 'MF' is a non-profit organization. The main objective of MF is to treat, with surgery of the highest standard, poor and needy persons throughout India who are suffering from congenital and facial deformities like Cleft Lip, Cleft Palate, Craniofacial deformities, etc., which affect then not only cosmetically but also functionally and psychologically.

For that purpose Maaya Institute for Skull and Facial Deformities intends to fund the Craniofacial and Cleft Surgeries at 'MGM Institute'.

B. MGM Institute of Health Sciences, Kamothe, Navi Mumbai – 410 209 is established as Deemed to be University under Section '3' of UGC Act, 1956 vide Government Notification No. F.9-21/2005-U.3 (A) dated 30.08.2006 issued by the Government of India, Ministry of Human Resource Development, Department of Higher Education, New Delhi. MGM Institute of Health Sciences is also registered under the Societies Registration Act, 1860 and BPT Act of 1952.

MGM Medical College & Hospital, Kamothe, Navi Mumbai is a well established constituent unit of 'MGM Institute' mainly catering to Health Care activities in Navi Mumbai and in the rural areas nearby.

MGM Hospital, Kamothe is well equipped with 750 bedded hospital with all in-house modern and latest facilities in Health Care.

C. The parties, therefore, to the extent feasible desire to enter into a co-operative, joint effort ('the Collaboration') to substantially increase the number of Craniofacial and Cleft reconstruction surgeries, through financial, technical and other support from 'MF".

D. The purpose and details of the collaboration are described in **Attachment 'A'**

I. OBJECT OF THE AGREEMENT

The object of this agreement is to spell out the conditions of the cooperation between the parties and of the support and assistance provided by 'MF'.

The contribution of MF to the cooperation consists in bearing the costs and expenses for the medical treatment and care of a certain number of persons suffering from congenital and facial deformities, who lack the means to pay these costs.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

II. TERM AND EFFECTIVE DATE

Funding of the collaboration shall begin as on _____(the 'Effective Date') and shall continue until _____ (the 'Funding Period'), unless extended or terminated as provided in the Renewal of Termination sections below.

III. OBLIGATIONS OF THE PARTIES

A. MGM INSTITUTE OF HEALTH SCIENCES ('MGM INSTITUTE')

1. 'MGM Institute' shall engage surgeons empanelled by 'MF' (**Refer Attachment 'C'**) as panel consultants and provide in house anaesthetists. In the event of complex surgeries or in house anaesthetists are unavailable, 'MF' shall engage services of anaesthetists empanelled by 'MF' who shall be panel consultants of 'MGM Institute' with prior approval of 'MGM Institute'.

2. "MGM Institute' shall make a full and thorough review of available resources from all departments of MGM Medical College Hospital, Kamothe, Navi Mumbai – 410209 and MGM Dental College and Hospital, Kamothe, Navi Mumbai as promised to 'MF' at the time of preliminary medical inspection. A consultation room for the purpose of the use of 'MF" Consultants and Speech Therapist will be provided, subject to availability.

3. Care of patients 'MGM Institute' in collaboration with the surgical team, will follow guidelines & protocols (Attachment E) laid down by 'MF' in selecting patients for treatment, using methods of treatment & necessary documentation. ('SAFETY AND QUALITY IMPROVEMENT PROTOCOL INCLUDING INSURANCE').

4. 'MGM Institute' shall provide 'MF' with complete patient information for each surgical case conducted through funding of the collaboration. 'MGM Institute' shall provide these completed records to 'MF' on a continuous basis.

5. 'MGM Institute' will submit monthly statement signed and sealed by the concerned authority for the cases conducted for which complete information has been supplied by 'MGM Institute' in detail and format prescribed (Attachment F) by 'MF'.

6. Immediately following 'the Effective Date, 'MGM Institute' will implement credentialing and monitoring procedures in accordance with

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

'MF's Safety and Quality Improvement Protocol (Attachment G). 'MGM Institute' acknowledges that -

(i) 'MF' has developed the Protocol for the express purpose of ensuring and maintaining high safety standards, quality improvement and quality control

(ii) The adoption and continued implementation of the Protocol by 'MGM Institute' is a condition to 'MF's obligations hereunder. In the event that any patient is harmed in any manner that is not in the ordinary course of cleft and craniofacial operations (Sentinel Event: death of the patients), 'MGM Institute' will immediately notify 'MF" of such event and

(iii) Implement the review process (Attachment G) set forth by 'MF' for Sentinel Event Protocol. As part of the Protocol, 'MGM Institute' specifically undertakes to report all sentinel events within 24 hours of the event's occurrence using 'MF's Reporting Form.

7. On a semi-annual basis, 'MGM Institute' shall meet with the representatives of 'MF' to evaluate the progress of the Project. At the time of each meeting, 'MGM Institute' will provide 'MF' with a narrative report, based on the case sheets and cases done by 'MF' surgeons documenting the progress of the collaboration. Included in this report should be a monthly breakdown of the number of surgeries performed, split up the categorization of surgical treatment. The parties will agree upon the date and time of each of the meetings.

8. 'MGM Institute' agrees to participate in 'MF' CLP Database (A free, global, cleft and craniofacial care database) by submitting the completed patient record information, which includes the patient consent form to share this information(which will be filed at the 'MF' office), besides the surgery.

At the conclusion of one year, 'MGM Institute" will submit a written report that includes progress of the Project to date and outlining the specific programs planned for the coming year.

At the end of one year, a duly authorized representative of 'MGM Institute' shall provide to 'MF' a certificate confirming the use of the Funded Amount.

B. MAAYA FOUNDATION ('MF')

1. 'MF" will contribute financial support as per Attachment 'B'.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

2. The funded Amount will be for the exclusive services provided by 'MGM Hospital', such as infrastructure & clinical support services. 'MGM Hospital' shall prefer invoice on a monthly basis, by 5th of the succeeding month. All payment of the month in concern will be made at the end of the succeeding month. The payments shall be made in the name of '**MGM Hospital**', Kamothe, Navi Mumbai – 410209.

3. 'MF" will provide 'MGM Institute' with a team of empanelled surgeons to conduct surgeries after accreditation by 'MGM Institute.

4. 'MF" will provide guidelines and protocols (Attachment H) for treatment & management of patients & patient services.

5. 'MF' shall ensure that patients are operated at the earliest.

C. DISPUTES

All disputes relating to this agreement shall be subject to the jurisdiction of Courts at Mumbai only.

IV. REPRESENTATIONS OF THE PARTIES

A. 'MGM INSTITUTE'

'MGM Institute' is validly existing and in good standing duly registered under Societies & Trust Act, and has the requisite authority to carry on its activities as of now being conducted. Any changes to this status shall be reported immediately to 'MF'.

B. 'MF'

'MF" is not-for-profit Trust, as defined by Indian Societies and Trusts Act, duly registered, validly existing and in good standing under the laws of India and has the requisite corporate authority to carry on its business as of now being conducted. Any change to this status shall be reported immediately to 'MGM Institute'.

V. RENEWAL

At the review at the end of the financial year, which will be on a yearly basis, representatives from 'MGM Institute' and 'MF' will meet to assess the progress of funding efforts. The decision to continue the project will be in consultation with both the said organizations involved – 'MF' and 'MGM Institute'. A minimum of 90 days notice is to be issued if either 'MF' or 'MGM Institute' wishes to terminate the agreement.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

VI. INFRASTRUCTURE REQUIREMENTS

Services to be provided by 'MGM Institute' for each patient at Charitable Ward Rates:-

1. Admission / Case Sheet
2. All routine investigations (As necessary) – Blood tests, ECG, Electrolytes, Serology, Chest X-Rays
3. Paediatric review (as required)
4. Physician review (as required)
5. ENT review (as required)
6. O.T. procedure
7. Available ICU facilities
8. Concessional / Charitable Ward stay as required
9. Suture removal / Sedation / O.T.
10. Medicines

VII. PUBLIC RELATIONS

'MF' reserves the right to publicize the cooperative efforts between the two parties through the use of literature, photographs, video film production and other media. 'MF' will also issue press releases and have the option to hold press conferences to announce the project and its progress only over the duration of the funding period. Both parties agree to be receptive to assisting in each other's efforts for publicity and / or additional fund raising. 'MGM Institute' acknowledges that the words 'Maaya' and the logo of 'MF" are the exclusive intellectual property of 'MF'.

The parties agree that all rights of and for publication of every kind and nature concerning the co-operation between them lie with both 'MF' and 'MGM Institute' (e.g. Photographs, Press, TV, Radio, Internet, Video). They will aid one another in its efforts to publish its mutual activities. They grant each another, without prior consent, authority to use its name and / or corporate logo when publishing their co-operation only during the funding period or the duration of the project.

'MGM Institute' agrees to refer in its own publications to the cooperation with 'MF'.

'MGM Institute' will affix or display at an appropriate place a name plate at a place and of a size considered appropriate by 'MGM Institute' with the following inscription:-

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

VIII. PROJECT MANAGEMENT & ADMINISTRATION

'MGM Institute' will report all clinical & administrative matters to the Centre Director of the Craniofacial Project. Dr. Krishna Shama Rao who will work with Dr. Gaurav Shekhar Deshpande from 'MGM Institute' who will be responsible for services provided, management of the centre, for communication and collaboration with MF.

Similarly, Dr. Rasika R. Jagtap from 'MGM Institute' who will be complete responsible for services provided, management of the centre for communication and collaboration with 'MF' will report all clinical and administrative matters to the Centre Director of the Cleft Project – Dr. Chetana.

IX. LIABILITY

Surgeons of MF', Anaesthetists of 'MF' and 'MGM Institute' and other medical professions working for the 'MF' project from 'MGM Institute' will assume liability for all medical treatment, interventions.

'MGM Institute' agrees, during and after termination to indemnify 'MF', its affiliates, members, officers, directors, employees, agents and representatives (each such person, an "indemnified Party") against all losses, damage, liability and expenses incurred as a result of a violation of this agreement and from all claims, damages, causes of action or suits of any persons arising from medical treatment, intervention and care and from all acts and omissions in connection with the performance of this agreement, except to the extent 'MF' surgeons / anaesthetists are legally liable for the operation done and treatment given by them.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

"MGM Institute' shall be solely responsible for compliance with all laws, statutes, ordinances, orders or codes of any public or governmental authority pertaining to this agreement, and for payment of all taxes, permits, license and registration fees and other charges or assessments arising out of the establishment and operation of the co-operation. Both 'MF' and 'MGM Institute' are indemnified from the said responsibilities.

X. TERMINATION

A. This agreement may be terminated by either party without assigning any reasons, by giving 90 days notice of its intention to do so, in writing to the other or at the end of the period of this agreement, if not renewed.

B. Notwithstanding the above, either party reserves the right to terminate this agreement by giving one month's notice (30 days), at its sole discretion, in the event of fraud, gross violation of medical standards or willful and malafide misrepresentations of facts.

C. This agreement shall also stand terminated forthwith if so directed by any statutory body or government department acting within the framework of the law.

D. On the termination of this agreement, 'MGM Institute' shall return all records, publicity material, brochures, etc., pertaining to the Project, and furnish to 'MF' a full accounting of the disbursement of funds and expenditures incurred under the grant up to the effective date of termination.

E. All equipments that may be funded by MF for the Maaya Institute for Skull and Facial Deformities at 'MGM Institute' shall remain the property of 'MF'. In the event that the collaboration stands terminated, 'MF' reserves complete rights to repossess the said equipments & instruments and re-deploy it to another Centre.

F. On termination 'MF' shall pay the unpaid balance of all expenses incurred by 'MGM Institute' as agreed by 'MF' for funding.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

XI. AMENDMENT

This Agreement may not be amended or modified except by an instrument in writing signed by, or on behalf of, 'MGM Institute' and 'MF'.

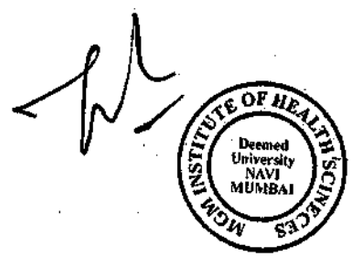
XII. NON DISCLOSURE

The contents of this agreement are privileged and confidential, and both parties undertake not to divulge the same to any third party without the prior, express written permission of the other. The only exceptions to this will be their duly appointed legal attorneys and advisors, or duly empowered statutory bodies and government agencies acting within the requirements of the law. Both parties also undertake to institute all reasonable steps to ensure that the confidentiality is maintained within their respective organizations.

XIII. OTHERS

A. This agreement is on a 'principal-to-principal' basis and it does not confer any right to either party to represent the other, act on its behalf as its agent or authorized representative, issue public statements, make commitments of any kind or claim any relationship beyond the one provided in the agreement. It is explicitly acknowledged by both parties that the collaboration does not constitute a partnership.

B. In the event of any dispute arising out of this agreement, both parties accept and acknowledge that the laws of India shall apply, and the same shall be resolved by arbitration as per the Arbitration and Reconciliation Act 1996.



IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the dates written below:

FOR MAAYA FOUNDATION	FOR MGM INSTITUTE OF HEALTH SCIENCES
MR. SHIVA GANESH CHAIRMAN	DR. SUDHIRCHANDRA N. KADAM VICE CHANCELLOR
MRS. RASHMI K. RAO COO	Prof. Z. G. Badade Registrar, MGM Institute of Health Sciences Kamothe, Navi Mumbai-401209
Seal:	Seal :
Dated:	
Place:	
Witness No. 1 Full Name: Signature:	Witness No. 2 Full Name: Signature:

ATTACHMENT: "A"

PROJECT SUMMARY

Title of Project: MF – Craniofacial and Cleft Programme at 'MGM INSTITUTE'.

Project Description / Objectives:

It is estimated that approximately 60,000 children are born with this birth defect in India each year. A large majority of these children (estimated at 80%) grow into adulthood without receiving any reconstructive surgery for want of money. The goal of the MF Cleft Programme at 'MGM Institute' is to perform significant number of cleft reconstructive surgeries and craniofacial surgeries by providing a full and comprehensive rehabilitation package of services to as many affected children as possible.

Funding support to achieve this objective will be provided by MF as part of its global commitment to helping children born with cleft lip and cleft palate. Surgeries will be conducted through the 'MGM Institute'

It is estimated that as a result of this funding, at least 300 reconstructive surgeries that include cleft / craniofacial surgeries will be performed per financial year. The financial support for surgeries is further outlined in **Attachment 'B'**. If it is anticipated that the actual number of cases is likely to exceed these projections, a prior written request for additional funding based on the same formula and on the same terms will be favorably considered, but approval shall be at the sole discretion of MF.

FOR MAAYA FOUNDATION	**FOR MGM INSTITUTE OF HEALTH SCIENCES**
MR. SHIVA GANESH **CHAIRMAN**	**Dr. SUDHIRCHANDRA N. KADAM** **VICE CHANCELLOR**
MRS. RASHMI K. RAO **COO**	**DR. Z.G. BADADE** **REGISTRAR** **Prof. Z. G. Badade** **Registrar,** **MGM Institute of Health Sciences** **Kamothe, Navi Mumbai-401209**
SEAL:	**SEAL :**

ATTACHMENT: "B"

SCHEDULE OF FUNDING SUPPORT BY CATEGORY OF SURGERY

FINANCIAL SUPPORT STRUCTURE:

Category	INTERVENTION / TYPE OF SURGERY PAYMENT IN INDIAN RUPEES / PER SURGERY			
	CLP (SIN)	CLP (DIN)	MAXILLO-FACIAL	CRANIO-FACIAL
Hospital	14,000.00	17,000.00	30,000.00	
Orthodontics / Dental	1,000.00	3,000.00	3,000.00	
Speech Therapy	200.00	200.00	200.00	
Patient Transport	600.00	600.00	600.00	
Patient Welfare	500.00	500.00	500.00	
Project Manager	1,000.00	1,000.00	1,000.00	
Search & Awareness	1,200.00	1,200.00	1,200.00	
Total	**18,500.00**	**23,500.00**	**36,600.00**	**95,000.00**

FOR MAAYA FOUNDATION

MR. SHIVA GANESH
CHAIRMAN

MRS. RASHMI K. RAO
COO

SEAL:

FOR MGM INSTITUTE OF HEALTH SCIENCES

Dr. SUDHIRCHANDRA N. KADAM
VICE CHANCELLOR

DR. Z.G. BADADE
REGISTRAR

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-401209

SEAL :

ATTACHMENT : "C"

EMPANELMENT OF SURGEONS

The following surgeons have been empanelled by the Medical Advisory Board of MF.

Prof. Dr. Krishna Shama Rao – Craniofacial Surgeon
Dr. Chetana K – Maxillofacial Surgeon
Dr. Gaurav Shekhar Deshpande- Maxillofacial Surgeon
Dr. Rolson Sandeep Kumar – Maxillofacial Surgeon
Dr. Arvind Bhateja –Neuro Surgeon
Dr. Banu Prakash – Neuro Surgeon
Dr. Kiran Prasad - Anaesthetist
Dr. Bhagyashree - Anaesthetist
Dr. Suhas Prabhakar - Surgical Fellow
Mrs. Rashmi K Rao – Speech Therapist

The additions of care providers for each specialty from 'MGM Institute' shall be updated in subsequent agreement, once nominated by 'MGM Institute'.

FOR MAAYA FOUNDATION	**FOR MGM INSTITUTE OF HEALTH SCIENCES**
MR. SHIVA GANESH **CHAIRMAN**	**Dr. SUDHIRCHANDRA N. KADAM** **VICE CHANCELLOR**
MRS. RASHMI K. RAO **COO**	**DR. Z.G. BADADE** **REGISTRAR** **Prof. Z. G. Badade** **Registrar,** **MGM Institute of Health Sciences** **Kamothe, Navi Mumbai-401209**
SEAL:	**SEAL :**

ATTACHMENT : "D"

The nominated care providers for each speciality from 'MGM Institute of Health Sciences' Navi Mumbai are:-

1. Dr. Gaurav Deshpande - Oral and Maxillofacial Surgery
2. Dr. Jyotsna S. Galinde - Oral and Maxillofacial Surgery
3. Dr Rasika Jagtap Deshpande - Periodontics and Oral Implantology
4. Dr Sachin Doshi - Orthodontics.
5. Dr Sabita Ram- Prosthodontics
6. Prof. Dr. Ashok Kumar - Neuro Surgery
7. Dt. Neeraj Patni - General Surgery
8. Dr. Deepika Sathe - Anesthesiology
9. Mrs. Bhavna Lala - Audiometrist & Speech Therapist

Dr. Z.G. Badade
Registrar
MGM Institute of Health Sciences

MGM INSTITUTE OF HEALTH SCIENCES
Deemed University NAVI MUMBAI

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Seal: **Kamothe, Navi Mumbai-401209**

ATTACHMENT: "E"

GUIDELINES AND PROTOCOLS FOR PATIENT CARE

Cleft Lip and Palate and Maxillofacial Surgery patients will be selected by the In-charge of the particular cleft center, but all Craniofacial surgery cases will be have to be pre-approved by the medical director of Maaya Foundation in advance.

1. Clinical Photographs, necessary facial scans, investigations will have to be performed before the craniofacial surgery cases are sent to the Medical Director for approval.
2. Children undergoing surgical repair to clefts will be accommodated in a children's surgical environment at, to reduce the risk of transmission of infection by children admitted as medical emergencies.
3. The inpatient area should be fully staffed by RSCN trained nurses.
4. Resident paediatric, surgical and anaesthetic staff who are experienced in the management of fluid balance, pain control, airway and respiratory problems must be available at all times on both sites.
5. Ideally there should be a Paediatric Specialist Registrar resident on the unit or rapidly available on call.
6. Together with the surgeon, the peri-operative care of children should be the responsibility of anaesthetists trained in paediatric anaesthesia and the facilities of a Paediatric Intensive Care Unit (PICU) should be easily available with a protocol for the transfer of the few patients who will need paediatric intensive care.
7. There should be adequate opportunity to assess the child prior to surgery and there should be appropriate facilities and equipment available for postoperative monitoring.
8. Appropriate facilities for parents, cares and children are essential. Some will have travelled very long distances to the centre for treatment: it is essential that facilities are available both for parents and for other appropriate family members. These will include accommodation, parking, food, laundry and be in accordance with those expected at the tertiary centres. Overnight accommodation should be guaranteed for a minimum of one, but preferably both parents.
9. All parents will be informed about the hospital travel costs scheme. A designated member of the team (staff) should inform patients about benefits and other assistance which may be available to them.

Dr. Z.G. Badade
Registrar
MGM Institute of Health Sciences

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Seal: **Kamothe, Navi Mumbai-401209**

ATTACHMENT: "F"

FORMAT OF BILLING TO MAAYA FOUNDATION

Sr No.	Name of the patient	Age	Sex	Date of Surgery	Procedure	Date of Discharge	Follow-up	Remarks	Type of Billing	Amount

Dr. Z.G. Badade
Registrar
MGM Institute of Health Sciences

Seal:

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-401209

ATTACHMENT: "G"

SAFETY AND QUALITY IMPROVEMENT PROTOCOLS

Safety Protocols:

The following essential items should be present at all times during and post-surgical procedures.

1. Oxygen:

   The Anaesthetist is to confirm prior to the start of any surgery that a separate reserve oxygen supply is in place for and dedicated to each operating table. A reserve supply, an average of a tank per 2 – 3 beds, must also be available in the Recovery Room. A reserve supply of one tank per ward must also be available in Post-Operative areas.

2. Blood:

   The surgeon has to confirm the blood group of all cleft palate, Maxillofacial and Craniofacial Surgery patients and adequate blood of the patient's group has to be reserved on the day of the surgery, in case need be.

3. Emergency Drugs:

   The Anaesthetist should confirm before the start of the surgery, the availability of adequate stock of emergency and life-saving medicines. The paediatrician can also help the Anaesthetist in arranging the drugs. The Nurse In-charge should inspect all drugs on routine basis to check for expiry and replace the drugs after the expiration date.

4. Post-operative management:

   Rigorous monitoring of the patient in the recovery room and post-operative wards is mandatory. The recovery room nurse must be qualified in paediatric advanced life support, in case of emergency. The recovery room and post-operative ward must be equipped with a monitor capable of pulse oximetry and a suction machine for the exclusive use of post-operative patients.

5. Sterilization:

   All instruments that will be used for surgery and post-operative care must be sterile. The surgical instruments should be autoclaved using indicator strips to confirm the sterility. All procedures should be followed using aseptic principles in accordance with the Universal policy of asepsis.

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-401209

Dr. Z.G. Badade
Registrar
MGM Institute of Health Sciences

Seal:

MGM INSTITUTE OF HEALTH SCIENCES
Deemed University
NAVI MUMBAI

ATTACHMENT: "H"

Guidelines and Protocols for Treatment and Management of Patients and Patient services

1. **Age**: Patient should be at least 6 months of age for cleft lip surgery and 12 months for cleft palate. Maxillofacial and Craniofacial surgery patients can be younger if the Medical Director of Maaya foundation has approved the case and Anaesthesiologist are competent to manage the patient. In such case Anaesthetist trained in paediatric anaesthesia is highly recommended.
2. **Surgery selection**: Cleft patients will be selected by the In-charge of the particular project. Maxillofacial and Craniofacial Surgery patients will have to be pre-approved by the Medical Director.
3. **Scheduling**: Patients younger than 2 years will be posted early in the day. If two patients of same age are present, then cleft palate should be given preference. Cleft palate patients should be avoided as last patients of the day, if possible.When scheduling Maxillofacial and Craniofacial surgery patients, a bed must be reserved in the paediatric ICU. The paediatric intensivist must be informed in advance for post-operative management.
4. **Patient factors**: The minimum weight of the patient for cleft lip surgery should follow the WHO guidelines. The patient should be at least two SD from normal. Any patient below this recommended range should be enrolled in the nutrition program and surgery deferred until adequate weight and Hb is attained. In case of low Hb, the patient will be counselled by the Paediatrician and relevant medications to improve the Hb will be given to the patient. The patient has to be followed up at regular intervals to check for the increase in Hb. Under NO circumstances should Pre-operative blood transfusion to improve Hb be administered. Blood transfusion should be limited to post-operative patients in whom excessive blood loss has happened during the surgery.
5. **Surgery Technique**: The attending surgeon will be the best guide on the selection of the technique of the surgery. If the surgeon is not credentialed or is a trainee, the in-charge of surgery should be making the decision and the surgeon will operate under complete and direct supervision. Maaya Foundation will NOT take responsibility of the surgery if not performed by a Maaya Foundation empanelled Physician.
6. **Postoperative Medications**: The In-charge of the particular cleft and craniofacial project will decide on the use of post-operative medications. This includes, antibiotics, analgesics and other medications as necessary.

Prof. Z. G. Badade
Registrar,
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-401209

Dr. Z.G. Badade
Registrar
MGM Institute of Health Sciences

Seal:

No.SR/WOS-A/LS-1118/2015 (G)
Government of India
Ministry of Science & Technology
Department of Science & Technology

Technology Bhavan
New Mehrauli Road
New Delhi-110 016
Dated 12.09.2016

ORDER

Sub: Financial approval of the project under Women Scientist Scheme A (WOS-A) entitled "Genetic and phenotypic analysis of fucosyltransferase-2 (FUT-2) gene in Mumbai population."

PI Ms. Kshiitija Suhas Rane Yadav, MGM Medical College & Hospital Educational Campus, Junction of NH-4 and Sion Panvel Expressway, Sec.1, Kamothe, Navi Mumbai-410209, Mahashtra.

Sanction of the President is hereby accorded to the above mentioned project at a total cost of ₹ **22,00,000/-** (Rupees Twenty two Lac only) for a duration of Three year. The items of expenditure for which the total allocation of ₹ **22,00,000/- (recurring)** has been approved for Three year are given below:

Sl. No.	Heads	1st Year	2nd Year	3rd Year	Total
A.	*Non-Recurring* (Capital Items)				
	Equipments: Nil	----------	----------	----------	----------
B.	*Recurring*(General)				
	Fellowship for M.Sc@ ₹ 30,000/-	3,60,000/-	3,60,000/-	3,60,000/-	10,80,000/-
	Consumables	2,70,000/-	2,70,000/-	2,60,000/-	8,00,000/-
	Contingencies	20,000/-	20,000/-	20,000/-	60,000/-
	Travel	20,000/-	20,000/-	20,000/-	60,000/-
C.	Overhead	67,000/-	67,000/-	66,000/-	2,00,000/-
D.	Total of Recurring Grant (B+C)	7,37,000/-	7,37,000/-	7,26,000/-	22,00,000/-
E.	GRAND TOTAL (A+D)	7,37,000/-	7,37,000/-	7,26,000/-	22,00,000/-

2. Overhead expenses are meant for the host institute towards the cost for providing infrastructure Facilities and benefits to the staff engaged in the project, etc.

3. Sanction of the grant is subject to the conditions as detailed in website www.online-wosa.gov.in.

4. Sanction of the President is accorded to the payment of ₹ **7,37,000/-** (Rupees Seven Lac Thirty Seven Thousand only) as first installment of **recurring grant** as per following budget heads during the year 2016-2017:

Demand No.77 Department of Science & Technology
3425 Other Scientific Research (Major Head)
60 Others (Sub-Major Head)
60.200 Assistance to other Scientific Bodies (Minor Head)
55 Disha Programme for Women in Science
55.01 Disha Programme for Women in Science
55.01.31 **Grants-in-aid General** for the year 2016-2017 **(Plan Expenditure-General)**

Dean
MGM Medical College, Navi Mumbai
Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

This release is being made under the **Disha Programme for Women in Science.**

Contd..p/- 2

VC: For information fr.
20/9/16

MGM Institute Of Health Sciences
INWARD NO. 8045
DATE: 19/9/16
REF: DZPAC

prove

(120)

5. The Sanction has been issued under the powers delegated to the Ministries and with the concurrence of IF Division of Department of Science & Technology vide their Concurrence Diary Number C/313/IFD/2016-17 dated 19.04.2016.

6. The institute will furnish to the DST, Utilization certificate and an audited statement of accounts pertaining to the grant immediately after the end of the each financial year. As this is the first grant being released for the project, no previous U/C is required.

7. The Institute will maintain separate audited accounts for the project; If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest earned should be reported to DST. The interest thus earned will be treated as a credit to the institute to be adjusted towards further installment of the grant.

8. The amount of ₹ 7,37,000/- (Rupees Seven Lac Thirty Seven Thousand only) as recurring grant will be Disbursed to the **Vice Chancellor, MGM Institute of Health Sciences, Kamothe, Navi Mumbai-410209, Mahashtra** by means of electronic transfer as per the details given below:

Institute name	:	MGM Institute of Health Sciences
Account No	:	0183104000252522
Bank Name	:	IDBI Bank
Branch	:	39-41, Sector 11, C.B.D. Belapur, Navi Mumbai
IFSC code	:	IBKL0000183

9. As per Rule 211(1) of GFRs, the accounts of the project shall be open to inspection by the sanctioning authority/audit whenever the institute is called upon to do so.

10. This sanction has been entered Sl. No.....in the Register of Grants (2016-17).

Singh

(Vandana Singh)
Scientist-D

Copy forwarded for information and necessary action to :-

1. The Director of Audit (CW & M-II), AGCR Building, IP Estate, New Delhi-110 002.
2. Copy with two spare copies of the sanction to the Drawing & Disbursing Officer, DST, Cash Section.
3. The Vice Chancellor, MGM Institute of Health Sciences, Kamothe, Navi Mumbai-410209, Mahashtra.
4. Dr. D.S. Joshi, MGM Medical College & Hospital Educational Campus, Junction of NH-4 and Sion Panvel Expressway, Sec.1, Kamothe, Navi Mumbai-410209, Mahashtra.
5. Ms. Kshiitija Suhas Rane Yadav, MGM Medical College & Hospital Educational Campus, Junction of NH-4 and Sion Panvel Expressway, Sec.1, Kamothe, Navi Mumbai-410209, Mahashtra.
6. Pay & Accounts Officer, DST, New Delhi
7. Accounts Section, DST, New Delhi
8. Head, KIRANDivision
9. Sanction Folder.
10. COA, DST, New Delhi
11. IFD DST, New Delhi
12. KIRAN Secretariat

Singh

(Vandana Singh)
Scientist-D

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : विज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद्

INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029
V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR. POST BOX 4911, NEW DELHI - 110 029

No. 5/10/FR/18/2014-RCH Dated: 19.4.2017

The Director,
MGM Institute of Health Sciences,
Sec-01, Kamothe,
Navi Mumbai-410209

Subject: Continuation for 2nd year of "Ad-hoc" project entitled "**Impact of radiations from cell phone towers and cell use on health of pregnant women, neonates and infants: A multidisciplinary collaborative effort**" under Dr. Maninder Singh Setia.

Dear Sir,

The Director General of the Indian Council of Medical Research sanctions the of above-mentioned scheme with an allotment **Rs.** 35,76,696/- **(Rupees Thirty Five Lakh Seventy Six Thousand Six Hundred and Ninety Six Only)** as detailed in attached statement for the 2nd year from 20/03/02018 to 19/03/2019 subject to the following conditions. The grant will be released to the head of the Institute in installments during the financial year on receipt of the demand in the prescribed form (Appendix-I) as indicated below:

Budget: **Rs.** 35,76,696/-

While asking for the release of the installment it may be ensured that the amount for the pay and allowances of the staff that are actually in position is included.

The other terms and conditions will remain the same as mentioned in this office letter of even number dated.

These issues with the concurrence of the Finance Division vide
RFC No. RCH/Ad-hoc/25/2016-2017 Dated: 9.3.2017

The receipt of this letter may kindly be acknowledged.

Yours faithfully,

Administrative Office
for Director General

Copy to gather with a copy of the budget statement forwarded for information to:

1. Accounts V Section, ICMR, New Delhi. The expenditure involved on this account is met from the provision made under head Ad-hoc for the financial year.
2. Finance Section
3. I.R.I.S. Section
4. Dr. Maninder Singh Setia, Epidemiologist, Dept. of Epidemiology, MGM Institute of Health Sciences, Sec-01, Kamothe, Navi Mumbai-410209

for Director General

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai-410 209

STATEMENT

Date of start: 20.3.2017
Duration: 3 years
IRIS No.: 2014-0184
RFC No. RCH/Ad-hoc/25/2016-2017
Dated: 9.3.2017

Project Entitled: "**Impact of radiations from cell phone towers and cell use on health of pregnant women, neonates and infants: A multidisciplinary collaborative effort**" under Dr. Maninder Singh Setia.

(20/03/02018 to 19/03/2019)

		2nd Year
(i)Staff	**SRF** (Medical) Rs.28,000/- PM +30% HRA Rs.(36,400/-).	4,36,800/-
	SRF (Non-Medical) Rs.28,000/- PM +30% HRA Rs.(36,400/-).	4,36,800/-
	Data Entry Operator (1) Rs.17,000/-PM(10% Increment)	2,13,120/-
	Field Worker (2)18,000/-PM(10%increment)	4,51,200/-
	Laboratory Tech. (1)Rs. 18,000/-PM(10%increment)	2,25,600/-
(ii) Cont.		
Recurring	Chemicals, diagnostic Kits, reagents, glassware etc, Radiological examination.	15,00,000/-
	AMC Travel	1,00,000/- 50,000/-
(iii)	Overheads(without equipment, Travel & AMC)@5%	1,63,176/-
Total		**35,76,696**

Rs. 35,76,696/- **(Rupees Thirty Five Lakh Seventy Six Thousand Six Hundred and Ninety Six Only)**

Admn. Officer
For Director General

Testing Agreement

This Testing Agreement ("**Agreement**") dated Twenty Ninth day of May Two Thousand Seventeen (2017) ("**Effective Date**")

by and between **Indian Institute of Technology, Madras** ("**Institute**") c/o the Center for Industrial Consultancy and Sponsored Research, Delhi Avenue, IIT Madras, Chennai 600 036 represented by its authorized signatory Dean, IC & SR.

AND

MGM institute of Health Sciences, Navi Mumbai through the MGM Institute's University Department of Physiotherapy having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 **(Hereinafter referred to as the Organization).**

WHEREAS

1. The Institute has developed certain Assistive Devices (the "**Products**") which could be used for enabling mobility in persons with locomotor impairments (the "**Purpose**")

2. Professor Sujatha Srinivasan, TTK Center for R2D2, Department of Mechanical Engineering at the Institute together with certain research scholars at the Institute have developed the Products, the intellectual property which is owned exclusively by the Institute.

3. The Institute contemplates that after the development and manufacture of the product, it will be necessary to test the said Product in certain controlled conditions (the "**Testing**").

4. The Organization has the required infrastructure and facilities to conduct the test is willing to participate in the Testing of the Products with the Institute upon terms and conditions as set out herein. The Institute has inspected the said available infrastructure, facilities, interacted with the staff and employees and has approved the same.

The Parties hereto have therefore mutually agreed as follows:

1. SCOPE OF WORK

1.1 Conduct of the Testing.

The parties agree to conduct the Testing in a controlled environment based upon the terms and conditions contained in this Agreement and in terms of the protocol to be mutually agreed between the Institute and the Organization prior to the time of the Testing. The organization shall get clearance from the Institutional Review Board and Ethics committee and communicate the same to the Institute, which will be final and binding both the parties.

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of U.G.C. Act, 1956)
Navi Mumbai-410 209

CENTRE FOR IC & SR
IIT MADRAS

1.2 **Care and Skill:**

The Organization, its employees and staff will:-

a) exercise all due care, diligence and skill necessary for carrying out testing activities;
b) use reasonable endeavours to complete the agreed work within the time specified;
c) allocate sufficient staff time (with suitable qualification/experience) for the testing;
d) obtain the Informed Consent of the concerned patients;
e) keep the records of the patients and the Institute confidential;

1.3 **Principal Investigator**.

Dr. Sujatha Srinivasan, Associate Professor, Department of Mechanical Engineering of the Institute will serve as the principal investigator ("**Principal Investigator**") for the Testing. The Principal Investigator is not a party to this Agreement and acts solely as an employee of Institute.

1.4 The Institute will supply the Products to conduct the Testing as well as other materials as required, and also information for the purpose of the Testing. At the end of the Testing, the Institute will remove the Products unless otherwise agreed with the Organization in writing. The Organization is responsible for proper conduct of the test under the supervision of its domain expert.

1.5 The Organization shall provide a list of patients who have provided their written consent for participating in the testing of the Product after being informed by the organization of the product, its purposes, the probable inherent risks involved in the use of the product etc. (the "**Informed Consent**") to the Testing of the Products. The Organization acknowledges that it has been and shall ensure that it will fully inform the patients about the Product, the Testing Protocol and the Purpose of the Product before obtaining the patient's Informed Written Consent. The Testing Protocol will contain the details of the number of Products to be used during the Testing. The written consent format as approved by the parties hereto and generally accepted by the Ethical Committee for research on Human Subjects ,MGMIHSis enclosed herewith.

1.6 **Testing Report.**

All the reports (including the Testing Report), data, materials and Product used for the purpose of this Agreement shall be owned by the Institute and the Organization. With the prior mutual consent, the Institute or the Organization as the case may be use the Testing Report for any purpose as deemed necessary by the Institute or the Principal Investigator including internal research, teaching, archival purposes, publication or transfer to third parties. The Organization will keep, maintain and regularly update the testing report and shall upon demand in writing by the Institute, or their authorized representatives provide copies as requested. The final testing report will be submitted to the Institute as and when required by the Institute. The Organization will create a testing report at the beginning of the Testing and will include in the report the details in terms of the Testing Protocol including but

CENTRE FOR IIT MADRAS

not limited to the outputs of the Testing, financial reports, the originals of the Informed Consent obtained, comments from the participants etc (the "**Testing Report**").

2. MEETING OF THE EXPENSES

Costs and Expenses.

Institute will meet the costs and expenses of the organization (to the extent of the approved budget), within a period of 30 -45 days from date of receipt of the bills from the Organization. The payments shall be made in the name of MGM Centre of Human Movement Science.

3. INTELLECTUAL PROPERTY

3.1 Pre-existing Intellectual Property.

Ownership of inventions, discoveries, works of authorship, and other developments existing as of the Effective Date and all patents, ("**Pre-existing Intellectual Property**") is not affected by this Agreement. Neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party, except as may be expressly provided in any other written agreement between the parties.

3.2 Inventions.

"**Inventions**" shall mean all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by the Institute. Institute shall be the sole owner of all Inventions that are conceived, first reduced to practice or otherwise discovered or developed by the Institute or any of its employees or research scholars.

3.3 Intellectual Property Agreements.

Intellectual Property (IP) generated as part of or as a consequence of the Testing shall solely and exclusively belong to the Institute. The Organization shall inform the Institute if any IP is created and will co-operate and provide its consent for transfer of all rights to the IP to the Institute. The Organization will procure all consents and assignments from its employees to enable the transfer of exclusive ownership of IP to the Institute.

4. TESTING DATA

4.1 Testing Data.

Institute shall exclusively own and maintain all the Testing results and data (the "**Data**") and may use it for any purpose including for research, teaching, educational, archival or auditing purposes and may share this Data with any third party at its discretion. The Organisation shall with the prior approval of the Institute have the access, right, title or interest over such Data.

4.2 **Product for Testing.**

Institute shall provide the Product at the premises of the Organization to enable the Institute and Organization to conduct the Testing. The Organization is responsible for proper conduct of the test under the supervision of domain expert. Title and ownership of the Product will at all times remain with the Institute. Subject to the provisions of Clause 1.4. the Organisation will return the Product to the Institute at the conclusion of the Testing, less normal wear and tear.

5. CONFIDENTIAL INFORMATION

5.1 Institute and Organisation recognize that conducting the Testing may require the transfer of confidential or proprietary information between the parties. All documents, information, materials and data provided to Organization by the Institute will be considered confidential information of the Institute only if marked as "confidential" ("**Confidential Information**"). The Organization shall ensure that the information is shared only with those employees, staff or parties who have a need to know the Confidential Information and shall procure confirmation that all such parties agree to be bound by this Confidentiality Clause and terms of this Agreement. In consideration of the disclosure of any Confidential Information to the other, the Institute and the Organization agree that, for a period of this Agreement and for a further period of three (3) years from the date of expiry of this Agreement, they will:

(a) Not use the Confidential Information except as allowed in this Agreement;
(b) Not use the Institute's Confidential Information without an appropriate patient authorization and/or consent and as allowed in this Agreement.
(c) Not disclose to third parties any of the Confidential Information belonging to the other party without the express written consent of the disclosing party except in accordance with this Agreement; and
(d) Take precautions as normally taken with the receiving party's own confidential and proprietary information to prevent disclosure to third parties.

5.2 The obligation of confidentiality does not apply to Confidential Information that is:
(a) publicly available through no fault of recipient;
(b) disclosed to the recipient by a third party;
(c) already known to the recipient at the time of disclosure;
(d) developed by the recipient without reference to the Confidential Information; or
(e) required to be disclosed by law, regulation, or court order.

For the purposes of this Agreement, the Testing Report and any Data shall be deemed to be the Confidential Information of the Institute.

6. PUBLICATION

6.1 The basic objective of research activities at Institute is the generation of new knowledge and its expeditious dissemination for the public's benefit.

CENTRE FOR IC SR IIT MADRAS

Organisation will provide all reasonable cooperation with Institute in meeting this objective.

6.2 Notwithstanding any terms to the contrary in this Agreement, Institute and organization retain the right at their discretion to publish/present results of the Testing with mutual consent.

7. TERMINATION

The Testing will continue until the Testing is completed by the Organisation. Institute may terminate this Agreement if the Organization breaches this Agreement or does anything to delay or hinder the Testing process; termination will be immediately effective upon the receipt of written notice from the Institute to the Organization. Similarly the termination can be done by the organization, and it becomes effective upon e-mail communication from the person who had signed this agreement or equivalent or above authorized person. It is further provided that such notice will not be served unless there is serious breach by the Institute.

8. NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

Indian Institute of Technology Madras:
Dean (IC & SR)
Centre for Industrial Consultancy and Sponsored Research
IIT Madras, Chennai 600036

MGM Institute's University Department of Physiotherapy
MGM Institute of Health Sciences
Navi Mumbai, India

9. PUBLICITY

9.1 Neither party will identify the other in any promotional advertising or other promotional materials to be disseminated to the public or use the name of any faculty member, employee, or student or any trademark, service mark, trade name, or symbol of the other, including without the other party's prior written consent.

9.2 Notwithstanding anything to the contrary, Organisation agrees to allow publicly registered information about the Testing to appear on Institute Directory website.

10. INDEMNITY

The Organization will indemnify and hold harmless the Institute, its employees, Investigator, staff and students from any loss, damage, claim (including legal costs) that may arise due the negligence or default of the Organization.

CENTRE FOR IC & SR IIT MADRAS

11. NO WARRANTIES

The Institute makes no warranties, express or implied, as to any matter whatsoever, including, without limitation, on the product or the results of the testing or any invention, process or product, whether tangible or intangible, conceived, discovered, or developed by it.

12. LIMITATION OF LIABLITY

The Institute shall not be liable for any indirect, consequential or other damages suffered by organisation or any of the testing patients including, but not limited to, damages arising from loss of data or delay or termination of the testing, or from the use of the results of the testing, or any such invention or product.

13. FORCE MAJEURE

The parties will not be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond Institute's control, such as accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

14. MISCELLANEOUS

14.1 **Assignment.** Neither party may assign this Agreement without the prior written consent of the other party.

14.2 **Survival.**
Any of the sections that include any other rights and obligations under this Agreement which by their nature should survive, shall survive the expiration or termination of this Agreement.

14.3 **Divisibility.**
If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.

14.4 **Independent Contractors.**
Institute and Organisation are independent contractors and neither is an agent, joint venture partners, or partner of the other.

14.5 **Order of Precedence.**
In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other agreement concerning this Testing between the Parties and their employees, the terms of this Agreement will prevail.

14.6 Entirety.
This Agreement represents the entire agreement and understanding between the parties and their employees with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

14.7 Amendments.
The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of the parties.

14.8 Counterparts.
This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

IN WITNESS WHEREOF, these duly authorized representatives of the parties hereby execute this Agreement, including all the terms and conditions which follow.

INDIAN INSTITUTE OF TECHNOLOGY, MADRAS

Name :
Designation : Dean (IC&SR)
Date : 29th May 2017

डीन (आई.सी. एवं एस.आर.)
DEAN (IC & SR)
भा.प्रौ.सं. मद्रास
I.I.T. MADRAS
चेन्नै/CHENNAI - 600 036

Principal Investigator

Name : Dr. Sujatha Srinivasan
Department : Mechanical Engineering
IIT-Madras

Date : 29th May 2017

MGM Institute of Health Sciences,
Navi Mumbai

Registrar
29th May 2017

Organization

Dr. Rajani Mullerpatan
MGM Institute's University Department of Physiotherapy, Navi Mumbai.

Date : 29th May 2017

NEW MEMBER AGREEMENT

This agreement is made and entered into on this 15th day of October, 2015 between;

Indian Institute of Technology, Bombay, a research and educational institution in technology and engineering disciplines established by a special act of Parliament of Republic of India having its office at Powai, Mumbai-400 076, India, hereinafter referred to as 'IITB' and **MGM Institute of Health Sciences**, Kamothe Navi Mumbai, 410209

MGM Institute of Health Sciences, Kamothe Navi Mumbai registered under societies Act, 1860 and having its registered office address at MGM campus, sector 1, Kamothe Navi Mumbai 410209 hereinafter referred as "MGM Institute of Health Sciences".

WHEREAS A Healthcare Consortium was formed vide a Consortium Agreement dated 7th September, 2011 between Indian Institute of Technology, Tata Memorial Centre, National Institute of Research in Reproductive Health, King Edward Memorial Hospital and Span Diagnostics Ltd (the 'Consortium Agreement' -Annexure -A) for the objectives and modes of collaboration as contained therein.

WHEREAS in pursuance thereof a Healthcare Consortium was formed to carry out and effectuate the purposes under the said Consortium Agreement with the aforestated founding partner organizations as Members thereof. The Healthcare Consortium has undertaken and started many health care activities/projects and initiatives as envisaged under the said agreeement.

WHEREAS the MGM Institute of Health Sciences has shown its interest, intends to and is keen to join and partake in the activities of the said Healthcare Consortium vide its letter/proposal dated 10th April 2015 to the Consortium.

WHEREAS In view of the aforesaid letter/proposal reflecting the desire of MGM Institute of Health Sciences intending to become a Member of the Healthcare Consortium, the Advisory Committee has accepted/approved such a proposal of the MGM Institute of Health Sciences, to become a new Member of the Healthcare Consortium, in its Board meeting dated 10th April 2015. Further, the Advisory Committee has approved and authorized IITB to enter into an agreement with MGM Institute of Health Sciences for inducting in the Healthcare Consortium as a New Member based on the condition that such intending New Member agrees to the terms of the Consortium Agreement.

Now, therefore, the Parties hereto, agree to the following;

(1/2)

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai-410 209

1. The MGM Institute of Health Sciences hereby agrees that in addition to the terms of this agreement, it shall be subject to, bound and governed by the terms and conditions of the said Consortium Agreement (Annexure 1).

2. The MGM Institute of Health Sciences, hereby agrees that, upon execution hereof, it shall be assigned/accorded the status of a Member in the Healthcare Consortium and shall duly discharge or partake in all activities of the said consortium as per the terms of the said Consortium Agreement and the guidelines issued by the Advisory Committee from time to time.

3. The said Consortium Agreement (annexed hereto as Annexure 1) and the terms thereof are incorporated in its entirety herein by reference and form an integral part of this agreement.

4. IITB is executing this agreement with the MGM Institute of Health Sciences as a confirming party for inclusion of the MGM Institute of Health Sciences as a Member of the said consortium, as authorized by the Governing Council.

IN WITNESS WHEROF, the authorized representatives of the parties hereto, have executed this New Member Agreement as set forth below;

MGM Institute of Health Sciences, Kamothe, Navi Mumbai

By: _____

Name:Lt. Gen. Dr. Shibban .K. Kaul

Title:Pro Vice Chancellor

Date: 15th October, 2015

By: _____

Name: Dr. Rajani Mullerpatan

Title: Prof – Director, Physiotherapy

Date: 15th October, 2015

INDIAN INSTITUTE OF TECHNOLOGY BOMBAY, FOR CONSORTIUM

By: _____ 26/10/15

Name: Prof. K. P. Kaliappan

Title: _____

Date:

(2/2)

Dean
MGM Medical College, Navi Mumbai

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, NEW DELHI

No 58/2/2014-BMS By Special Post Date: 16.3.2015

The Dean,
MGM Medical College, Kamothe, Navi Mumbai

Subject:- Sanction of budget allotment for the new Research proposal entitled "Development natural alternatives to synthetic dipeptidyl peptidase 4 inhibitors for diabetes with metabolic syndrome

Sir,

The Director General of the ICMR sanctions the above mentioned research scheme initially for the period of one year from 1.3.2015 subject to extension up to the total duration specified in para 4 below:-

1. The Director General of the Council also sanctions the budget allotment of Rs.9,34,000/- as detailed in the attached statement for the period from 1.3.2015 to 29.2.2016 The grant-in-aid will be given subject to the following conditions.
2. 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.
3. 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.
4. The demand for payment of the subsequent installment of the grant should be placed with the Council in the prescribed proforma. The approved duration of the scheme is Three YEAR. The annual extension will be given after review of the work done on the scheme during the previous year.
5. Five copies of the annual progress report in the attached prescribed proforma should be submitted to the Council 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.

The receipt of this letter may please be acknowledge.

Yours faithfully,
Admn. Officer
For Director General

Copy together with a copy of the budget statement forwarded to information to Dr. Ipsita Roy, Dr. Ipsita Roy, Professor, Deptt. Of Pharmacology, MGM Medical College, Kamothe, Navi Mumbai - 410209

2 Accounts. V. for information.

3. Copy together with the budget forwarded to Budget Section [Finance Section] for compilation of the Council Budget
4. IRIS Cell No. 2012-07910

HOSPITAL ANALYSIS SHEET

NAME OF THE HOSPITAL-	MGM MEDICAL COLLEGE AND HOSPITAL	Application no
		HSP281011292
Type of Hospital-	Private	
DISTRICT-	Raigad	
Location-		
NO OF BEDS-	400	
All mandatary documents are received:	Yes	
Whether multispeciality/single speciality:	Multispecialty	
# of specialist available in the hospital:		
Remark		
Rate % Accepted	70	
EDC Date	01/02/2012	
EDC Approval	Yes	No
CAO Remark :		
CAO Approved :	Yes	No

Signature

भारतीय गैर न्यायिक

भारत

पचास रुपये रु.50

FIFTY RUPEES Rs.50

सत्यमेव जयते

INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

AT 830566

शेख स्टॅम्प वेंडर, कळंबोली

बैत KL5/35/1, सेक्टर-३ई कळंबोली. फोन: २७४२४१३१

पुरवठ्याचा दिनांक 2 0 JAN 2012

उपकोषागाराचे नांव-पनवेल, जि. रायगड.

उपकोषागार अधिकारी पनवेल - रायगड.

अनुज्ञप्ती क्रमांक पनवेल ५/१९९६-९७

(सौ. शेख एस. पी. के.) स्टॅम्प वेंडर

Memorandum of Understanding between

MD India

&

MGM Medical College & Hospital, Kamothe ,Navi Mumbai

MAIL RECEIVED

EMPANEL DEPT.

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

भारतीय गैर न्यायिक

भारत

पचास रुपये

रु.50

FIFTY RUPEES

Rs.50

सत्यमेव जयते

INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

30 JAN 2012

पुरवठ्याचा दिनांक उपकोषागाराचे नाव पनवेल जि. रायगड.

उपकोषागार अधिकारी पनवेल - रायगड.

अ. न. [illegible] दिनांक [illegible]

शेख स्टॅम्प वेंडर, कळंबोली T 830567

बैत KL5/35/1, सेक्टर-३ई, कळंबोली. फोन: २७४२४१३१.

नांव [illegible]

रहिवासी [illegible] वतीने [illegible]

अनुज्ञप्ती क्रमांक पनवेल ५/१९९६-९७

(सौ. शेख एस. पी. के.) स्टॅम्प वेंडर

Dean

MGM Medical College, Navi Mumbai

Dean.

M. G. M. Medical College & Hospital

Kamothe, Navi Mumbai - 410209

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent

M. G. M. HOSPITAL, KAMOTHE

Medical Superintendent

M. G. M. HOSPITAL, KAMOTHE

MEMORANDUM OF UNDERSTANDING

Government of Maharashtra has decided to revamp the existing Jeevandayee Yojana of covering catastrophic illnesses of poor by making it more comprehensive and inclusive. In pursuance with this, State is launching **"Rajiv Gandhi Jeevandayee Arogya Yojana" (RGJAY)** in a phased manner in order to improve access of Below Poverty Line (yellow ration card holders) and Above Poverty Line (orange card holders) families to quality medical care for identified specialty services requiring hospitalization for surgeries and therapies or consultations through an identified network of health care facilities.

The scheme envisages the treatment for the identified 972 procedures/ailments and 121 follow up procedures and it provides the beneficiary a total cashless facility.

This Agreements is made at Mumbai on this 14th the day of February 2012 between MDIndia Healthcare Services (TPA) Pvt. Ltd, a company duly registered under The Companies Act, 1956, having its Head Office at S. No 46/1, 3rd Floor, E- Space, Building A-2, Vadgaon Sheri, Nagar Road, Pune-411014, Maharashtra, hereinafter referred to as **"MDIndia"**, National Insurance Company, herein referred as **"Insurer"**, and Rajiv Gandhi Jeevandayee Arogya Yojana Society of Government of Maharashtra, **herein referred as "RGJAYS"** (which expression shall unless it be repugnant to the context or meaning thereof shall deem to mean and include its successors and assignees) of the ONE PART

And

MGM Medical college & Hospital, Kamothe, Navi Mumbai

represented by Managing Superintendent / Director / Proprietor and having its Registered Office at **Plot No.1&2, Sector18, Near Mumbai Pune Express High way,Kamothe , Navi Mumbai** hereinafter referred to as **"PROVIDER"** (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and assignees) of The OTHER PART.

WHEREAS, MDIndia has got mandate from Insurer who in turn have got the mandate from the Government of Maharashtra to cover families with annual aggregate income equal to or less than Rs. 100000 and yellow ration card holders (BPL) or Orange ration card holders (APL) or Antyodaya or Annapurna card holders belonging to 8 (eight) districts namely, Mumbai City, Mumbai Suburban District, Dhule, Raigad, Solapur, Nanded, Amravati, and Gadchiroli, of the State of Maharashtra (**"Beneficiary families"**) against Specified surgical / Therapeutic procedures (972 procedures and 121 follow up procedures) for which purpose MDIndia is creating a network of service Providers.

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Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

The Provider desires to join the said network of Providers and is willing to extend cashless medical facilities for the surgical/Therapeutic procedures as per "Rajiv Gandhi Jeevandayee Arogya Yojana Scheme Manual on Surgical & Medical treatments for Cashless Treatment of the eligible families of RGJAY society", to members of Below Poverty Line (BPL) and Above Poverty Line (APL) families identified either by RGJAY Health Card or yellow / orange Ration Card / Antyodaya Card / Annapurna card ; and referred to them by the MD India under the RGJAY Health Insurance Scheme of the Government of Maharashtra.

Role definition:

1. **RGJAY society:** Rajiv Gandhi Jeevandayee Arogya Yojana society: **Role:** Empowered by Government of Maharashtra to implement the scheme.
2. **National Insurance Company: Insurer-** Role: Covers the risk.
3. **TPA: Third Party Administrator, MDIndia Healthcare (TPA) services Pvt Ltd-** Role: Administrator of the scheme.

Now this agreement witnesses as under.

Definitions

IRDA': Insurance Regulatory and Development Authority.

1.1 **'Hospital':** Hospital Registered under Bombay Nursing Home Act with minimum 50 beds.

1.1.1 **HOSPITAL / NURSING HOME :** Means any Government institution or Private institution in Maharashtra established for indoor medical care and treatment of disease and injuries and should be registered under Bombay Nursing Home Registration (Amendment 2005) Act and PNDT Act &/or Human Organ Transplant Act 1994 (Wherever Applicable).

1.1.2 **Infrastructure and Manpower (General):**

Should have at least **50** inpatient medical beds with adequate spacing and supporting staff as per norms.

Should have Separate Male and Female General Wards

Fully equipped and engaged in providing Medical and Surgical facilities for the respective specialties

In-house round the clock basic diagnostic facilities for biochemical, Pathological and radiology tests such as Calorimeter/ Auto analyzer, Microscope, X-ray, E.C.G, USG, etc.

Shall be able to facilitate round the clock advanced diagnostic facilities either In-House or Tie-up facility with a nearby Diagnostic Center with a qualified pathologist.

Fully equipped Operation Theatre of its own wherever surgical operations are carried out with qualified nursing staff under its employment round the clock.

Post-operative ward with ventilator and other required facilities (wherever required).

ICU facility with requisite staff

Fully qualified doctor(s) of **modern medicine should** be physically in charge round the clock.

Casualty/duty doctor/Appropriate nursing staff.

Availability of Qualified/trained paramedics round the clock; availability of specialists in the concerned specialties and support fields within short notice.

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Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

Shall be able to facilitate round the clock Blood Bank facilities either In-House or Tie-up facility with a nearby Blood Bank.

Shall be able to facilitate round the clock Ambulance facilities either own or Tie-up facility with a nearby Service Provider.

Maintaining complete record as required on day-to-day basis and is able to provide necessary records of the insured patient to MDIndia /Insurer/RGJAYS or their representative as and when required.

Having sufficient experience in the specific identified field.

Shall have all necessary infrastructure required for preauthorization round the clock to be obtained electronically by direct access to the web portal of the society.

Hospital should maintain line list of procedures carried out & treatment given in following Proforma.

Name of patient	Age	Gender	Address	Diagnosis	Name of surgery / Treatment	Date of admission	Date of Surgery	Date of discharge

1.1.3 Specific separate requirements for super specialty procedures as agreed upon in addendum to the MOU.

1.1.4 **Hospital shall provide following additional benefit to the Health Card Holders issued on basis of (Yellow ration card holder) and APL (orange ration card holders with Aggregate family Annual income = or < Rs. 100000),Antyodaya and Annapurna card beneficiary families related to identified systems:**

Provide space and separate RGJAY counter/kiosk as per the design for Aarogyamitras.

Provide Computer with networking (dedicated broadband with minimum 2mbps speed), printer, scanner, bar code reader and digital camera as per specifications given in Annexure A In case the Provider does not have the above as per the specifications defined then MDIndia will provide the same and the cost will be recovered from the claim payment due to the Provider for the treatment given to beneficiaries. The cost of the installation will be recovered and then balance if any made payable to the Provider.

Provide free food for the patient when hospitalized.

Provide transport/transportation charges for patient by cash (onetime transport cost by State Transport or second class rail fare (from Hospital to residence of patient only))

Free OPD consultation.

Free diagnostic tests and medical treatment required for beneficiary families irrespective of surgery.

Provide the services of a dedicated Medical Officer to work as Medical Coordinator (MCO) for the scheme who will be responsible to the Society and MDIndia for doing various activities under the scheme including Health Camps, Follow-up of referred patients from camps, diagnosis, outpatient details, E-preauthorization, Surgeries, Feedback on the patient's condition and services offered by the hospital during hospital stay of the patients, discharges, deaths if any, follow-up free consultation of the patients and distribution of medicines after discharge etc.

MDIndia shall provide CUG (Closed User Groups) Connection to all MCOs.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

Provide follow-up free consultation diagnostics and medicines under follow-up packages for 121 identified procedures annexed as provided under the scheme, the package amount will be directly reimbursed to the hospital by MDIndia.

Minimum one free Health Camp in a village in a week for the screening of the beneficiary families suffering from the identified ailments. Hospital may have a mobile team with diagnostic equipment and team of doctors as specified by the Society for this purpose. Villages shall be identified by the Society in consultation with district administration and communicated to the hospitals. Hospital shall provide services of Medical Camp Coordinator (MCCO) for organization of health camps. The Hospital shall follow the camp policy of the Society.

MDIndia shall provide CUG Connection to all MCCOs.

MDIndia will provide the Aarogyamitra Kiosk (computer with broad band connectivity, printer, scanner, bar code reader and digital camera etc.) & the same will be installed by MDIndia whose cost will be recovered from the claim payment due to the Provider for the treatment given to beneficiaries. The cost of the installation will be recovered and then balance if any made payable to the Provider.

1.2 **'Network Hospital' / NWH:** Hospital empanelled under RGJAY.

1.3 **'MOU':** Memorandum of Understanding between MDIndia, Insurer, & Empanelled Hospital.

1.4 **'Surgery / Surgeries':** means cutting, abrading, suturing, laser or otherwise physically changing body tissues and organs by qualified medical doctor who is authorized to do so

1.5 **'Therapy / Therapies':** Standard way of medical treatment to the patient as per the medical protocols of Allopathic medicine.

1.6 **'Treatment':** Medical management by qualified Doctor in the Network Hospital.

1.7 **'Aarogyamitra':** First contact person for RGJAY patient at Network Hospital.

1.8 **MCOs (Medical Coordinator)** - Medical Coordinator from the Network Hospital with minimum MBBS qualification to coordinate with RGJAY society / MDIndia.

1.9 **'MCCOs'** an Officer designated as Medical Camp Coordinator for the scheme to coordinate with RGJAY society / MDIndia through Aarogyamitra.

1.10 **'IEC':** Information, Education & Communication.

1.11 **'TAT':** Turn Around Time.

1.12 **'Pre-Authorization':** Pre-Authorization is a process by which an Insured Person obtains written approval for certain medical procedures or treatments, from RGJAY society / Insurer/MDIndia.

1.13 **'EDC':** Empanelment & Disciplinary Committee.

1.14 **CMRF:** Chief Ministers Relief Fund

2. Effective Date

This agreement will be in force for a period of three years from of the date of effectivity for Phase I and be automatically renewed for successive period of 3 years, unless either party notifies in writing to other party of its intention to terminate this MOU 90 days in advance. .The MOU will remain in force to service the beneficiaries irrespective of Insurer and Administrator as maybe appointed by RGJAYS. In case of Renewal intimation of Scheme by MDIndia, the Provider agrees to extend services to beneficiary families of RGJAY Scheme beyond the effective date until otherwise terminated and all the services rendered by the Provider shall be considered for subsequent renewal period as well at same terms and conditions as set forth with here under.

MAHATMA GANDHI HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

3. General Provisions

3.1 General Undertaking:

Provider warrants that it has all the required facilities for performing the enlisted surgeries/procedures/ therapies as specified in clause. No. 1.3.2

3.2 Minimum Bed Strength and Specialty Wise Bed Capacity

Provider declares that the hospital has the required number of bed capacity (50) under the scheme and will declare the specialty wise allocation of beds in the Proforma submitted below and uploaded in RGJAY society portal.

Total Bed Strength

Code	Specialty	Total No of Beds
S1	General Surgery	120
S2	ENT	30
S3	Ophthalmology	40
S4	Gynecology & Obstetrics	NA
S5	Orthopedics	60
S6	Surgical Gastroenterology	10
S7	Cardio Thoracic Surgery	10
S8	Pediatric Surgery	10
S9	Genito Urinary Surgery	20
S10	Neuro Surgery	10
S11	Surgical Oncology	10
S12	Medical Oncology	NA
S13	Radio Oncology	NA
S14	Plastic Surgery	10
S15	Polytrauma	22
S17	Prosthesis	*
M1	Critical Care	18
M2	General Medicine	160
M3	Infectious Diseases	*
M4.	Pediatric Intensive Care	NA
M4.	Neonatal Intensive Care	NA
M4.	Pediatric General	NA
M5	Cardiology	20
M6	Nephrology	10
M7	Neurology	10
M8	Pulmonology	30
M9	Dermatology	30
M10	Rheumatology	*
M11	Endocrinology	NA
M12	Gastroenterology	*
M 13	Interventional Radiology	*
	Others	8
	Total Number of Beds	638

*marked specialities are available beds are distributed under medicine, surgery & orthopaedics wards presently for the respective servises.

**** If specific beds are not allotted to that specialty please write "NA"**

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

3.3 Allocating up to 25% of beds in network hospital for RGJAY Patients:

Provider agrees to provide up to 25 % of their bed capacity available for occupancy by RGJAY beneficiaries for treatment under each specialty available in the hospital and under which the procedures are covered in the RGJAY Scheme.

3.4 Conduct of OP services :

3.4.1 Provider agrees to provide separate OP facilities for RGJAY patients by "Medical Coordinator" of the hospital (MCO) and Aarogyamitra(s).

3.4.2 Provider agrees to do general counseling for all OP patients to ascertain their eligibility under RGJAY to avoid later conversion of cash patients at a later date.

3.5 Conversion of cash patients into RGJAY:

Provider agrees to take a declaration from patient at the time of admission itself on the applicability or otherwise of RGJAY in his/her case. In emergency trauma cases, patients may be allowed 48 hours after admission to claim RGJAY Benefit. However the said will be applicable only if there is no other concurrent insurance cover of any other scheme or claim under CMRF.

3.6 Online Updating of Bed Occupancy:

Provider agrees to upload the bed occupancy under each specialty for which Hospital is empanelled as and when required.

3.7 The first point of contact for all the patients (out patients and in patients) coming under the Scheme will be the Aarogyamitra positioned at Network Hospital.

3.8 The Provider agrees to follow ALL the guidelines in rendering the services to RGJAY beneficiaries annexed hereto as part & parcel of this MOU and as to be updated from time to time and made available on the website. The Provider also agrees to follow and adhere to the guideline issued by the RGJAY society &/or MDIndia from time to time.

3.9 The Provider agrees to follow & adhere to the ON-LINE workflow of the RGJAY Insurance Scheme in providing services to RGJAY beneficiaries.

4 Eligibility Criteria:

The Provider agrees to follow the guidelines on eligibility criteria for admission of Patients under RGJAY Health Scheme as mentioned here under and the Following guidelines are re-emphasized by the RGJAY society to be followed by Network hospital in cases where clarifications are sought.

Health Card issued based on Valid Ration card by the RGJAYS / Antyodaya or Annapurna card will be the only criteria for the identification of beneficiary in the scheme.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

5 Specialty / Specialties Empanelled for

5.1 Provider hereby declares that the hospital has requisite infrastructure as per RGJAY guidelines in relation to specialty services for which Empanelment is done and agrees to provide quality diagnostic and treatment services as per the standard protocols.

5.2 Provider hereby declares that hospital did not exclude any other specialty service deliberately from the scheme in spite of having such facility and agrees to empanel for the specialties for which adequate infrastructure is available

5.3 The Hospital hereby declares that the bed capacity of the hospital is more than 50 with adequate infrastructure and manpower as per standard guidelines and agrees to provide separate male and female wards with toilet and other basic amenities.

5.4 The Hospital declares that it has a well-equipped ICU to meet the emergency requirements of the patients belonging to all categories empanelled for and agrees to facilitate round clock diagnostic and specialist services.

5.5 Specialties Provider agrees not to refuse admission of RGJAY patient in any Specialty where it has consultants and equipment. A minimum of 25% of bed capacity and of beds in each specialty have to be made available to RGJAY patients in network hospital.

5.6 Provider agrees to follow the guidelines issued by the RGJAY society /Insurer /MDIndia on specific specialties.

6 Empanelment

6.1 Infrastructure and Manpower (General):

Well-equipped operation theatre.
Casualty / 24 hrs. Duty doctor / appropriate nursing staff.
Availability of trained paramedics.
Post-op ward with ventilator and other required facilities.
ICU with concerned specialty.
Round the clock laboratory and radiology support.
Availability of specialists in support fields.
Facilities for Interventional Radiology and availability of concerned specialist.

6.2 Infrastructure and Manpower (Specific):

Provider agrees to provide the services as per the packages and adhere to the treatment protocols

The Provider will agree to quote batch no. of the drugs along with the bills.

The Provider agrees to submit the bar code, stickers of the implants used and empty pouch of the implant, wherever applicable.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

The Provider agrees to give patients feedback through Multimedia having webcam and mike. The provision for live viewing of the patient will be provided in the RGJAY society portal.

Provider will be able to provide necessary cashless diagnostic support round the clock including specialized such as CT, MRI, and emergency biochemical investigations.

Provider should put all necessary infrastructure required for Preauthorization round the clock.

For empanelment of laboratory services, the signatory should essentially be a qualified pathologist.

6.3 Specialties for which empanelment is done

No.	Specialty Service	Available /Not Available	Specialist Name	Degree	Regd. No
	SURGICAL SPECIALTIES				
1	**General Surgery**	Available			
	Qualified General Surgeon with post graduate degree in General Surgery	-do-	Dr. Topno Margaret Dr. Ali Reza	M.S.(Gen. Surg) M.S.(Gen. Surg)	56122 07239
	Well Equipped theatre facility with trained staff	-do-			
	Post-op with Ventilator Support	-do-			
	SICU Facility	-do-			
	Availability of support specialty of General Medicine, Pediatrics.	-do-			
1.a	**Laparoscopic Surgeries**	Available			
	Surgeon having requisite training and having performed at least 100 procedures for laparoscopic surgery (documentary evidence to be produced)	-do-	Dr. Ashok kalyanshetty	M.S.(Gen. Surgery)	077921
2	**Orthopedic Surgery**	Available			
	Qualified Orthopedic Surgeon	-do-	Dr. Alfven Vieira Dr. Sarabjeetsingh Kohali	M.S.(Ortho) M.S.(Ortho)	18044 27805
	Well-equipped theatre with C arm facility	-do-			
	Trained paramedics	-do-			
	Well-equipped Post-op facility with Ventilator Support	-do-			
	Round the clock lab support with CT,MRI	-do-			
3	**Gynecology and Obstetrics**	NA			
	Qualified Gynecologist				
	Expertise trained in laparoscopic procedure with minimum 100 performances				
	Well Equipped theatre				
	Post-op ventilator & Pediatric reconstruction facilities.				
	Support services of Pediatrician				

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No.	Specialty Service	Available /Not Available	Specialist Name	Degree	Regd. No
4	**Ophthalmology**	Available			
	Qualified Ophthalmologist ,trained vitreo Retinal and orthotics Surgeon	-do-	Dr. Bhagawat	M.S. (Gen. Surg) MCH(Ped.	9783
	Optometry facility	-do-			
	Well-equipped theatre facility	-do-			
5	**ENT**	Available			
	Qualified ENT Surgeon	-do-	Dr. Suman Rao Dr. Kalpana	M.S.(OTO-RHINO-LARINGOLOGY) M.S.(OTO-RHINO-LARINGOLOGY)	49196 14325
	Well-equipped theatre	-do-			
	Post-op with ventilator support	-do-			
	Audiology support	-do-			
6	**Cardio-thoracic surgery**	Available			
	CT Surgeon	-do-	Dr. Jayant Karbase Dr. Gopinath Rachmale	M.S. MCh (CVTS) M.S. MCh (CVTS)	34747 7464
	CT theatre	-do-			
	Cath –lab	-do-			
	Cardiologist support	-do-			
	Post-op with ventilator support	-do-			
	ICCU	-do-			
	Other cardiac infrastructure	-do-			
7	**Plastic Surgery**	Available	Dr. Subhash Jain	M.S. (Plastic Surgery)	67606
	Qualified Plastic Surgeon with MCh in plastic surgery or other equivalent degree recognized by MCI	-do-			
	Well Equipped Theatre	-do-			
	SICU	-do-			
	Post-op rehab / Physio-therapy support	-do-			
8	**Neurosurgery**	Available			
	Qualified Neuro-Surgeon (M.Ch.)Neurosurgery or equivalent	-do-	Dr. Ashok Hunde Dr. B.K. Acharya	M.S. MCh (Neurosurgery)	26802 87433
	Well Equipped Theatre with qualified paramedical staff	-do-			
	Neuro ICU facility	-do-			
	Post-op with ventilator support	-do-			
9	**Urology**	Available			
	Qualified urologist	-do-	Dr. Nitin Joshi Dr. Sumit Mehta	M.S. MCh (Uro) M.S. MCh (Uro)	63913 67418
	Well-equipped theatre with C-ARM	-do-			
	Endoscopes investigation support	-do-			
	Post-op with ventilator support	-do-			
	Sew lithotripsy equipment	-do-			

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No.	Specialty Service	Available /Not Available	Specialist Name	Degree	Regd. No
10	**Pediatric Surgery**	Available			
	Qualified pediatric surgeon	-do-	Dr. Aniruddha Bhagwat	M.S. MCh (Pediatric surgery)	9783
	Well-equipped theatre	-do-			
	Pediatric and Neonatal ICU support	-do-			
	Post-op with ventilator and pediatric resuscitator facility	-do-			
	Support services of pediatric	-do-			
11	**Surgical Gastroenterology**	Available			
	Qualified Surgical Gastro-Enterologist	-do-	Dr. N.L.Vyas	M.S.(Gen. Surg.) training from Galtofte university Denmark	001531/10 153
	Well Equipped Theatre	-do-			
	Endoscope equipment	-do-			
	Post –op with ventilator support	-do-			
	Centre Must have done at least 100 Endoscope Surgeries	-do-			
	SICU	-do-			
B	**MEDICAL SPECIALTIES**				
1	**General Medicine**	Available			
	Qualified General Physician with post graduate degree in General Medicine, Or Equal	-do-	Dr. Jaishree Ghanekar Dr. T.K.Biswas	M.D.(Medicine) M.D.(Medicine)	73750 25698
	AMC with ventilator support	-do-			
2	**Pediatric**	NA			
	Qualified pediatrician				
	NICU & PICU fully equipped				
	Round the clock Pediatric /Emergency service room with Pediatric resuscitation faculty				
3	**Cardiology**	Available			
	Qualified Cardiologist with DM or Equivalent Degree	-do-	Dr. V.D. Chavan Dr. R. G. Rathod	MD(Med.) DM(Cardiology) MD(Med.) DM(Cardiology)	35101 47834
	ICU Facility with cardiac monitoring and ventilator support	-do-			
	Hospital should facilitate Round the clock cardiologist services	-do-			
	Availability of support specialty of General Physician & Pediatrician	-do-			

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No.	Specialty Service	Available /Not Available	Specialist Name	Degree	Regd No.
3a	**Cardiac Interventions and Procedures**	Available			
	Qualified Cardiologist with experience in interventions and procedures	-do-	Dr. V.D. Chavan Dr. Sanjeevkumar Kalkekar	MD(Med.) DM(Cardiology) MD(Med.) DNB(Cardiology)	35101 2000/02/ 1342
	Fully equipped Cath lab Unit with qualified and trained Paramedics	-do-			
	Must have Backup CT Surgery Unit to perform Cardiac Surgeries	-do-			
	Centre Must have done at least 100 interventions'	-do-			
4	**Nephrology**	Available			
	Qualified Nephrologists with DM or Equivalent Degree	-do-	Dr. Ravindra Nikalge	M.D(Med.) DM(Nephrology)	89161
	Hemodialysis facility	-do-			
	AMC and Physician Support	-do-			
5	**Medical-Gastro Enterology**	Available			
	Qualified Gastro Enterologist with DM or Equivalent Degree.	-do-			
	Endoscopy facility	-do-			
	AMC and Physician Support	-do-			
	Centre Must have done at least 100 Endoscopic procedures	-do-			
6	**Endocrinology**	NA			
	Qualified Endocrinologist with DM or Equivalent Degree				
	AMC with ventilator and Physician Support.				
7	**Neurology**	Available			
	Qualified Neurologist with DM or Equivalent Degree.	-do-	Dr. Alok Banerjee	M.D(Med.) DM(Neurology)	19657
	EEG, ENMG, Angio-CT facility of Neurological study	-do-			
	Neuro ICU Facility with ventilator	-do-			
	Physician Support	-do-			
8	**Dermatology**	Available			
	Qualified Dermatologist with MD or Equivalent Degree.	-do-	Dr. Hema Jayrajani Dr. Shailaja S.	M.B.B.S.M.C.P.S M.B.B.S. Diploma of N.B.(Derm.& Ven)	37586 27866
	AMC and Physician Support.	-do-			

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No.	Specialty Service	Available /Not Available	Specialist Name	Degree	Regd No.
9	**Pulmonology**	Available			
	Qualified Pulmonologist	-do-	Dr. Pradeep potdar Dr. Mitali Naik	MD.(Resp. Med. MD.(T.B.)	45362 17642
	RICU facility	-do-			
	Spirometry and bronchoscope facility	-do-			
	Physician Support	-do-			
10	**Rheumatology**	NA			
	Qualified Pulmonologist				
	MICU Facility				
	Physician and Orthopedic Support				
	Physiotherapy Support				
C	**COMMISIONED SERVICES FOR CANCER THERAPY**				
1	**Cancer**	Available			
	Services of qualified Medical Oncologist	NA	Dr. Prashant Mullerpathan	M.S.(Gen Surgery) Fellowship in Surgical Oncology	74313
	Services of qualified Surgical Oncologist	Available			
	Services of qualified Radiation Oncologist if in-house Radiotherapy equipment	NA			
	Fully equipped Radiotherapy Unit	NA			
	SICU or tie up with nearest Radiotherapy center.	NA			
	Interventional Radiology	Available	Dr. Nikhil Karnik	M.B.B.S. DNB	2002/07/2655
	Availability of DSA equipment	-do-			
	Qualified and trained interventional radiologists	-do-			

7 Cashless Services under Package

7.1 The Provider agrees to provide total cashless transaction to the Beneficiary right from his reporting to discharge under the scheme.

7.2 Provider agrees to provide treatment as per the packages worked out by the RGJAY society. The package includes consultation, medicine, diagnostics, Implants, food, cost of transportation, hospital charges etc. In other words the package should cover the entire cost of patient from date of reporting to his discharge from hospital and for 10 days after discharge, making the transaction truly cashless to the patient. And under no circumstances shall charge any money extra within the treatment period of package.

7.3 The Provider agrees to issue a test requisition slip to the patient which will empower the patient to approach the concerned diagnostic/test centers within the hospital or otherwise and do the tests without any cash transaction. The details of the Tests done and their results will be uploaded in the portal by the MCO of the Provider.

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7.4 Provider agrees to keep all the RGJAY patients admitted till 10 days of postoperative or till patient recovered satisfactorily in all those cases where operation was performed.

7.5 The hospital agrees to the package to be authorized even for those patients who were admitted as non-RGJAY out of ignorance but subsequently identified as RGJAY beneficiary during the course of his/her stay in the hospital provided they are to make cash payment otherwise and if they are not covered under any other form of insurance. In the meanwhile any payment received from the patient shall be refunded immediately after getting pre-authorization approval and before discharge of the patient from the hospital duly obtaining a receipt from the patient.

7.6 Hospital shall assist and facilitate the patient to procure compatible blood for the surgeries and therapies. The Hospital shall provide blood from their own blood bank subject to availability within the package. In case of non-availability the hospital shall make efforts to procure from other blood banks, Red Cross, Voluntary organizations, etc. The Hospital shall also issue a copy of the request letter to the patient.

8 Gradation & Package Rates

8.1 The Provider agrees to allow MDIndia to assess the infrastructure and rate the hospital on multiple parameters. The Provider agrees to be graded by MDIndia and also have it accredited by concerned authorities if required.

8.2 The Package rates are given in the annexure & will form a part and parcel of the MOU and these will be the basis and binding for the treatment cost of various procedures.

8.3 The Package rates are the maximum rate indicated for each surgical procedure. Annexure B.

8.4 Provider has agreed to the continuation of the agreed tariff for the period of this agreement & thereafter in case of renewal for subsequent phases.

8.5 In the event of more than one procedure is being undertaken in one sitting other than those of routine/standard components of the surgical procedure, the package amount will be decided by the panel of specialists identified by Society in Consultation with treating doctor and decision of this committee will be final and binding on the hospital.

8.6 Provider under any circumstances will not refuse to undertake procedure on the ground of insufficient package.

8.7 In all other disputes related to package rates and technical approvals of preauthorization's the matter will be referred to a technical committee of the RGJAY society and decision of the committee is binding on the Provider.

9 Cost of evaluation of patients

The cost of various treatment/tests conducted on the beneficiary family members who are evaluated but ultimately do not undergo Surgery or Therapies will be borne by the Provider themselves and the Provider will not charge any fee for consultation and investigation from the Beneficiary.

10 Quality of Services

10.1 Provider agrees to provide separate and Free OPD consultation. However there will not be any discrimination to RGJAY patients vis-a-vis other paying patients in regard to quality of services.

10.2 Provider shall agree to provide free diagnostic tests and medical treatment for beneficiary families irrespective of surgery / Therapy required according to good business practices.

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10.3 The Provider will treat RGJAY Beneficiary families in a courteous manner and according to good business practices & as per the GMP/GCP guidelines wherever applicable.

10.4 The Provider will extend admission facilities to the Beneficiary families round the clock.

10.5 The Provider will have themselves covered by proper indemnity policy including errors, omission and professional indemnity insurance and agrees to keep such policies in force during entire tenure of the agreement.

10.6 Provider will ensure that the best and complete diagnostic, therapeutic and follow-up services based on standard medical practices / recommendations are extended to the Beneficiary.

10.7 The Provider agrees to provide quality service to the beneficiary by following Standard protocols for diagnosis and treatment. It is also mandatory for the Provider to assess the appropriate need and subject the beneficiary for Treatment / Procedure.

10.8 The Provider agrees to provide quality medicines, standard prostheses, Implants and disposables while treating the beneficiary families.

10.9 The Provider agrees to assist and cooperate with the medical auditing team from the RGJAY society / Insurer /MDIndia as and when required.

10.10 The Provider agrees to provide video recorded evidence of patient counseling before surgery in order to avoid legal complications / any adverse reaction by patients or Patient's relatives or by public in the event of unacceptable outcome.

10.11 The hospitals Morbidity and Mortality cases will be subject to scrutiny by the RGJAY society / Insurer / MDIndia.

10.12 The Provider agrees to take sole responsibility in submitting the patient details online and if any discrepancy is found in this regard the Provider agrees to abide by decisions of EDC.

10.13 The Provider indemnifies MDIndia/Insurer /RGJAY in full against all liability, loss, costs and expenses (including legal expenses) awarded against or incurred or paid by MDINDIA as a result of or in connection with breach by the Provider or any of its officers, employees, agents or representatives of any of the provisions of this MOU.

11 Services of Medical Coordinator

Provider will have a Medical Officer / Medical Officers designated as RGJAY Medical Coordinator/s (MCO) for the scheme to coordinate with Society through Aarogyamitra. The Provider agrees to submit the details of appointed MCO's.

The Provider should promptly inform /Insurer /MDIndia about change if any in the MCO designated during the tenure of the agreement.

11.1 The following will be the responsibility of MCOs (Medical Coordinator):

1. He / She will ensure that all required evaluation including diagnostic tests are done free of cost for all beneficiary families and the details of the same along with reports are captured in the RGJAY society portal.
2. He / She will upload the OP/IP status of the patient.
3. He / She will guide the patient in all aspects and sign the investigation request.
4. He / She have to cross check whether diagnosis is covered in the scheme. If doubtful about the plan of management then should coordinate with treating specialist along with Package list as specified in the RGJAY portal.
5. He / She should facilitate the admission process of Patient without any delay.

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6. After admission He / She will collect all the necessary investigation reports before sending for approval.
7. He / She will upload the admission notes and preoperative clinical notes of the patient.
8. He / She will ensure that preauthorization request is sent only for those who are on bed (IP)
9. He / She will ensure before sending Preauthorization that all documents like health card or valid ration card (yellow/orange) coupled with Aadhaar number, Patient photo and also necessary reports like CT Films, X-Ray films, Angio CD etc. are uploaded in the system.
10. He / She will coordinate with MDIndia and RGJAY society doctors as need arise.
11. Preauthorization kept pending from MDIndia and RGJAY society will be verified on a regular basis and necessary corrections to be done by MCO
12. He / She will furnish daily clinical notes (Per Operative and Postoperative).
13. He / She will upload 3 Photographs of the Patient taken preoperative bedside, immediate post-operative showing operation wound and at the time of discharge.
14. He / She will update surgery and discharge details and hand over signed copy of the summary along with follow-up advice in preprinted stationary supplied.
15. He / She will ensure free follow –up consultations, routine investigations and distribution of drugs to be supplied by the Provider to the beneficiary families.
16. He / She will ensure to update the details of on bed status of patients time to time as per the format on the display board placed at the Aarogyamitra Kiosk / reception desk.
17. The Provider will have a Data Entry Operator and each data entry operator will be linked to the respective MCO and the final responsibility of the data fed by the data entry operator will be vested on MCO of the Hospital. The Provider agrees to submit the details of Data Entry Operator.

11.2 Mode of communication

11.2.1 The Provider agrees to use the Closed User Group (CUG) mobile phone given by Insurer /MDIndia to MCOs & MCCOs exclusively for the purpose official Communications related to RGJAY Scheme. Any mis-utilization of CUG by the MCOs & MCCOs, then MDIndia reserves the right to initiate action against the service Provider.

11.2.2 The Provider agrees to use only RGJAY Messaging Services provided on the Web Portal for any kind of official communications related to RGJAY scheme. The Email-Ids of MCOs & MCCOs provided by the RGJAY society/ MDIndia will be used as their communication method.

12 Documentation and MIS

12.1 The Provider will ensure that documentation of RGJAY patients are done Using standard formats supplied / available online such as admission card, referral card, investigation slip, discharge summary etc.

12.2 RGJAY society/MDIndia /Insurer reserve the right to visit the Beneficiary and check his medical data with or without intimation as and when required.

12.3 The Provider will allow the General Managers / Deputy General Managers/ Field staff. / Doctors. Vigilance officials and other officials from the RGJAY society, Insurer and MDIndia to inspect the hospitals without obstruction and co-ordinate with them during Surprise and Regular Inspections.

12.4 Provider will furnish periodical reports to RGJAY society / MDIndia /Insurer on the Progress of the scheme as per the formats prescribed for this purpose.

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12.5 Provider will not give any document to facilitate the RGJAY patient to obtain any other relief like CMRF etc. Provider will not claim any other relief for the procedures covered under the scheme from any other source or schemes or insurance. Any deviation in this regard may attract delisting of the hospital and action as per decision of the EDC.

12.6 The Provider agrees to keep printouts of all online documents in the case sheet and make available as and when required for verification by field staff / doctors of the RGJAY society / Insurer/MDIndia.

13 Display of Boards & Banners

13.1 Provider agrees to display their status of preferred Provider of RGJAY Community Health Insurance Scheme at their reception / admission desks.

13.2 Provider agrees to display their status of specialties empanelled in RGJAY Community Health Insurance Scheme at their reception / admission desks.

13.3 Provider agrees to display availability of beds in the hospital and also display specialty wise bed occupancy under RGJAY Community Health Scheme at their reception / admission desks.

13.4 Provider agrees to display the process flow of RGJAY within the hospital at the RGJAY kiosk.

13.5 Provider agrees to make available of the list of diseases with package rates Covered under RGJAY community Health Insurance scheme in the form of Booklet supplied by the RGJAY society/ MDIndia at their reception / Admission desks.

13.6 Provider agrees to display other materials supplied by RGJAY society /MDIndia for the ease of Beneficiary families.

14 RGJAY Kiosk and Aarogyamitra Services

14.1 The Provider will allow RGJAY Assistance Counter / Kiosk to be established at the reception of the Provider free of cost.

14.2 The Provider will provide following infrastructure and network facility to the counter: computer, Printer, Scanner, Digital Camera, Webcam, Barcode reader, Mike, Speakers, Stationary etc. The System and other peripherals should be provided exclusively for the use of Aarogyamitra who can use the resources at any point of time.

14.3 The Provider will provide a dedicated 2mbps broadband connectivity to the Computer to be exclusively used by the Aarogyamitra to access the web for online MIS.E-preauthorization etc.

14.4 The Provider will allow Aarogyamitra access to the wards and patients data to facilitate onward transmission to the Company for e-pre-auth, claims, correct MIS etc.

14.5 The Provider will update the date of surgery, discharge / death of the beneficiary in the RGJAY society portal.

14.6 The Provider will intimate Aarogyamitra and MCO regarding emergency admissions of the Beneficiary during non-office hours.

15 Preference to Beneficiary families

15.1 The Provider agrees not to deny admission for the beneficiary for want of Preauthorization approval.

15.2 The Provider agrees to provide a separate ward for RGJAY Beneficiary families.

15.3 The Provider agrees to provide separate Operation Theatre and weekly schedules for the surgeries / therapies to be performed for the Beneficiary families.

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16 Capacity for Surgeries

16.1 The Provider agrees to handle a minimum number of cases in each specialty including trauma cases based on their available infrastructure as under:

	CATEGORY	SPECIALTY	Capacity to admit number of patients/Day (Bed Strength)
A	**MEDICAL SPECIALTIES**		
	General Medicine		30-32
	Critical Care		1-2
	General Medicine		
	Infectious Diseases		1-2
	Pediatrics		NA
	Neonatal Intensive Care		NA
	Pediatric Intensive Care		NA
	Pediatrics (General)		4-5
	Cardiology (Medical Management)		4-6
	Nephrology		4-6
	Neurology		4-6
	Endocrinology		NA
	Medical Gastroenterology		4-6
	Dermatology		6-8
	Rheumatology		2-4
	Pulmonology		6-8
B	**SURGICAL SPECIALTIES**		
	General Surgery		20-22
	Orthopedics		12-14
	ENT		6-8
	Ophthalmology		10-12
	Gynecology and Obstetrics		NA
	Cardiac Interventions		2-3
	Cardiothoracic Surgery		4-5
	Surgical Gastroenterology		4-5
	Genitourinary Surgery		4-5
	Neuro Surgery		2-4
	Pediatric Surgery		4-5
	Plastic Surgery		2-4
C	**SPECIAL SERVICES**		
	Cancer		
	Medical Oncology		NA
	Surgical Oncology		2-3
	Radiation Oncology*		NA

*Depending on bed availability more or less patients may be admitted.

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16.2 The Provider agrees to submit the vacancy level in pre-operative wards, ICU, Post-Operative wards and also upload the same in the RGJAY society portal on a daily basis.

17 Medical Camps

17.1 The Provider will conduct free medical camps at least once a week or 4 camps per month at the place specified by the RGJAY society to identify the members of the Beneficiary Families who may require surgeries covered under the scheme as per the schedule given by the RGJAY society/for such surgeries. The camp policy as given will be scrupulously followed.

17.2 The Provider will carry necessary diagnostic equipment to these free medical camps.

17.3 The Provider will provide preferably the screening services of concerned specialists namely Oncologists, Urologists, Cardiologists, CT Surgeon, Neurosurgeons, General Surgeon, General Physicians to the camp to facilitate better yield with respect to RGJAYS procedures (972). To ensure this, the empanelled hospitals will be allowed to hold joint camps too.

17.4 The Provider will submit the camp confirmation and indent online as given in camp policy in the prescribed format to RGJAY society/ MDIndia at least one week in advance of the stipulated date.

17.5 The Provider will inform all the stakeholders such as district Administration, concerned public representatives, PHC / AH / DH staff etc. well in advance for successful conduct of the camp.

17.6 The Provider will spread awareness about the camp through Publicity in Coordination with District Coordinator. Regional coordinator, PHC staff and Aarogyamitras.

17.7 The Provider will provide patient data to RGJAY society / MDIndia in the prescribed form at the end of the camp.

17.8 The Provider will enter the details of the patients screened and referred at the camps on the RGJAY society website on the same day of the camp.

17.9 The Provider will coordinate constantly with the Medical camps cell of the RGJAY society in all matters related to Medical camps.

17.10 The patients referred from the camp will be followed up and transported to the Hospital within 10 days of the camp unless the patient is not willing, in which case the same should be recorded and updated in the Website.

17.11 Provider will have an Officer designated as Medical Camp Coordinator (MCCOs) for the scheme to coordinate with RGJAY society / Insurer/MDIndia through Aarogyamitra. The Provider agrees to submit the details of appointed MCCO's as per the ANNEXURE. The Provider agrees to inform MDIndia, Insurer & RGJAY society about the Change in the MCCO designated if any, during the tenure of the Agreement.

The Provider will give the full time services of RGJAY Medical Camp Coordinator (MCCO) to coordinate all activities related to camps and Patient follow up from camps.

The following will be the responsibilities of Medical Camp Coordinator (MCCOs)

Confirmation of camps online and indenting online.
Carrying out the IEC activities within camp area at least 7 days before the Camp date.
Providing facilities like shamianas, chairs, screening enclosures.
Providing common medicines in the camps.
Arrange for distribution of incentives to the medical officers.

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Coordinating and ensuring participation of specialists.
Arranging the diagnostic equipment
Coordinate with PHC doctors / government Doctors, Public Representatives, SHG groups and Local Administration.
Raising claims online for the camps conducted.
Follow – up of patients referred from Camps as per requirement of the RGJAY
And other responsibilities mentioned on the website.

18 Admission of Beneficiary

18.1 Request for examination and if necessary hospitalization for surgical Procedures on behalf of the Beneficiary will made by the "RGJAY Help Desk" at Government Hospital or by the "RGJAY Assistance Counter / Kiosk" at Network Hospital.

18.2 Aarogyamitra at RGJAY Assistance Counter / Kiosk at the Network Hospital will coordinate with the Provider from the time of admission till discharge after the surgical procedure.

19 e-Pre- Authorization

19.1 Pre-authorization request will be sent only after admission and the patient will be there in the hospital as inpatient till final decision on the Preauthorization is made.

19.2 The Provider will submit the e-pre-authorization, after admitting the Patient as in-patient, on the RGJAY Website complete in all aspects including the signed copy of consent of the patient. All relevant test reports along with Digital photograph of the Beneficiary taken in the hospital should also be uploaded. Catheterization CD, MRI films, X-rays, Biopsy reports will be uploaded, and cytology and biopsy reports / slides should be submitted.

19.3 MDIndia undertake to approve the Preauthorization in consultation with the RGJAY society indicating the relevant package rates, maximum, within **12 working Hours** of the receipt of the request for pre-authorization form as well as the Required data and information online

19.4 The Provider agrees to update the surgery online immediately after performing the Surgery. However, the validity period of the preauthorization **is 30 days from the date of approval.** The Provider agrees to update clinical notes of ALL cases (both Pre & Post pre-authorization notes) in the Website on daily basis. If the surgery / therapy are not **updated within 30 days** after approval of pre. authorization, it will automatically get cancelled in the RGJAY Portal. The Provider should obtain fresh approval for the cancelled pre-authorization by mentioning valid reasons and MDIndia / Insurer /RGJAY society reserves the right to approve/reject the request of preauthorization. After Approval of pre-authorization, if the patient is not found on bed at the time of routine check by officials of RGJAYS/Insurer /MDIndia and in case the Provider is unable to present the patient during the routine check by officials of RGJAYS/Insurer /MDIndia, the RGJAY society/Insurer /MDIndia reserves the right to cancel the Preauthorization immediately without any intimation.

19.5 If the Provider is not able to conduct the operation within a reasonable Time for any reason other than medical such as non-availability of beds or specialists, the Provider will arrange for the operation to be conducted at any other appropriate Network Hospitals in consultation with MDIndia.

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19.6 The Provider agrees that the approval of Pre-authorization by RGJAY society / MDIndia is mere approval for eligibility of case for Assistance Under scheme and should not be construed as approval of choice of the Treatment & outcome consequences thereof which is sole responsibility of treating Doctor.

19.7 Any deficiency in documentation & ONLINE updation of data and protocols by the Provider which may lead to pending of Pre-authorization approval, the responsibility for such delay leading to delay in treatment & outcome is solely responsibility of the Provider.

19.8 The Provider agrees that any Rejection of Pre-authorization shall not be construed as denial of treatment to the patient and outcome thereof; it is a mere rejection of assistance under the scheme guidelines. The Provider agrees to exercise best of his judgment and counsel the patient about the alternate ways of providing such care including the option of referring the patient to Govt. Institution where such facility exists.

19.9 Preauthorization preferably will be given to the network hospital whichever does the preliminary screening either at the Medical camp or at the Hospital. Second pre-authorization for the same patient from different Network hospital will not be entertained for the same procedure unless medically warranted or surgical procedure is unduly delayed by the first Hospital without proper medical grounds.

19.10 MDIndia reserves the right to disallow the claim if the Surgery / Therapy are performed before any approval from MDIndia/RGJAY society and preauthorization is obtained at a later date keeping MDIndia/RGJAY Society in dark about the surgery /therapy.

19.11 The Provider agrees to send the enhancement requests before the Discharge of the patient through E-mail or by fax and follow the Enhancement guidelines and enhancement module manual in the booklet The Provider agrees to abide by the decision of Technical Committee and shall extend cashless facility to the patient.

19.12 **The Provider agrees to obtain emergency Telephonic Approval for Emergency cases only.** MDIndia/RGJAY society reserves the right to cancel the Emergency telephonic approval, if the Provider fails to update the pre-authorization **online within 72 hours of Emergency telephonic Approval.**

The Provider also agrees to perform the surgery / therapy Obtained through telephonic **intimation within 24 hours from the date** and time of telephonic approval. The Provider also agrees to update the surgery/ therapy done for telephonic instructions online mentioning the date & time along with specific remarks and photographic evidences while updating the online pre-authorization, starting from the telephonic intimations.

20 Transport of Patients

The Provider agrees to bear the cost of transport charges (one time transport cost by State Transport or second class rail fare (from Hospital to residence of patient only) incurred by the beneficiary) and agrees to arrange the same at time of Discharge and obtain acknowledgment from the patient accordingly. The Provider agrees to obtain signature of beneficiary on the acknowledgment sheet generated from the portal and upload the scanned copy & photograph to RGJAY Web portal.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

21 Free food to patients

The Provider agrees to provide free food of good quality to the patients as envisaged in the package rates either through in-house pantry or by making alternate arrangements like supplying from nearby canteen.

22 Discharge and Follow up

22.1 Intimation of the impending discharge of the Beneficiary need to be advised to RGJAY Assistance Counter at least one day before the discharge of the patient.

22.2 The discharge has to be done in the presence of MCO and Aarogyamitra concerned and update the details ONLINE.

22.3 At the time of Discharge the one time transport cost by State Transport or second class rail fare (from Hospital to residence of patient only) has to be reimbursed to the Patient, if the Hospital has not provided the transportation. The acknowledgment of receiving the amount for transportation has to be generated from the RGJAY society portal and the signed copy has to be uploaded.

22.4 Discharge summary will be generated from the RGJAY society portal in a pre- printed stationary to be supplied. The Discharge summary will consist of all the treatment details of the Patient at the Hospital and the follow up regime for the Patient including consultation and medication.

22.5 All the patients must be provided with follow-up medicines after discharge by the Provider as part of the package.

22.6 If the same Patient is coming back to the Hospital, the follow up details have to be uploaded in the RGJAY society portal.

22.7 **Satisfaction letter of the Patients has to be generated** from the RGJAY society portal and the signed copy has to be uploaded.

22.8 The MCO & Aarogyamitra should counsel the patient for all the precautions to be taken for the post-operative care.

22.9 All patients who require follow-up medicines will be advised by the Provider to come back on **11th day of discharge for** first follow up mandatory. The date of first follow-up will be generated by the RGJAY society portal along with the discharge summary.

22.10 The subsequent follow-ups for the above cases will be as per the follow-up Guidelines

22.11 The Provider will agree to provide follow-up services for a period of ONE YEAR under the Scheme.

22.12 The Provider will agree to provide free post-surgical physiotherapy services, wherever required for the agreement period.

23 Billing Procedure / Checklist for the Provider at the time of Patient's discharge

23.1 It is admitted and agreed that the Provider is aware that this MOU has Arisen for the purpose of implementation of the RGJAY intended for Beneficiary families in specified Districts of Maharashtra and accordingly the Provider will in no circumstance charge or seek any payment from the Beneficiary families but will look only to for indemnity, and that too only to the limits/schedule of fees in respect of procedures referred to earlier and Agreed to under this MOU.

23.2 Signature or the LTI of the patient / Beneficiary will be obtained on final Hospital bills and the discharge form.

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23.3 The Provider will submit the following: Original discharge summary, original investigation reports, **All original prescriptions, Procedure CD's, MRI films, X-rays, Post-Operative slides with Biopsy report, 3 Photographs** of the patient taken preoperative bedside, immediate post-operative showing operation wound and at the time of discharge, Case Sheet with Operation Notes Breakup of the bills (Room Rent, Investigations, Procedure charges & pharmacy receipt) etc. These are to be made available to for Claim payment, while submitting the bill. The copies of the Discharge summary signed by the Beneficiary will be uploaded in the web. A summary of the bills raised will also be uploaded.

23.4 Letter of satisfaction from the patient should also be obtained and sent along with the bills in prescribed format.

23.5 Provider should ensure that Chemo Therapy Drugs are physically administered to the Patients. Provider should produce bills by quoting batch no. with intact labels.

23.6 The Provider will have an Officer designated as Billing Head in order to follow the process of the online work flow. The Provider agrees to submit the details of Billing Head.

24 Payment Terms and Conditions

24.1 MDIndia /Insurer **agrees to pay all the eligible bills within 7 working days** electronically through NEFT / RTGS ; subject to Submission of all supporting documents including post-operative Investigations, daily Progress report and ICU charts.

24.1.1 The payments to the Provider are made by MDIndia **after deducting Taxes (TDS) as per prevailing IT Rules**, and accordingly MDIndia will issue the Form No. 16A at the end of Financial Year. Provider hereby agrees to comply with all the formalities required in fulfilling regulations of Income Tax Dept.

24.1.2 The expenses towards installation of the RGJAYS kiosk will be debited first towards payment and balance remaining if any paid to the hospital.

24.2 The Provider agrees to submit the core banking number, IFSC code to MDIndia to facilitate electronic fund transfer for settling the claims.

24.3 The Provider agrees to submit all the claims for the surgeries / Treatments performed within 60 days from the date of discharge of patient.

24.4 The Provider agrees to perform Surgeries / Treatment within 30 days from the date of expiry of this agreement for all the Pre-authorizations obtained during the period and submits the claim as per clause above.

25 Limitations of liability and indemnity

25.1 The Provider will be responsible for all commissions and omissions in treating the patients referred under the scheme and will also be Responsible for all legal consequences that may arise. MDIndia/Insurer /RGJAYS will not be held responsible for the choice of treatment and Outcome of the treatment or quality of the care provided by the Provider And should any legal complications arise and is called upon to answer, the Provider will pay all legal expenses and consequent compensation, if any.

25.2 The Provider admits and agrees that if any claim arises out of alleged Deficiency in service on their part or on the part of their men or agents, then it will be the duty of the Provider to answer such claim. In the unlikely event of MDIndia being proceeded against for such cause of action and

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M. G. M. HOSPITAL, KAMOTHE

any liability was imposed on them, only by virtue of its relationship with the Provider, and then the Provider will step in and meet such liability on their own.

25.3 Notwithstanding anything to the contrary in this Agreement, neither Party will be liable by reason of failure or delay in the performance of its duties and obligations under this Agreement if such failure or delay is caused by acts of God, Strikes, lock-outs, embargoes, war, riots, civil commotion, any orders of Governmental, Quasi-Governmental or local authorities, or any other similar cause beyond its control and without its fault of negligence.

25.4 The Provider undertake for applicability of terms and conditions mentioned and in all the MOUs executed for all the phases in-lieu of this MOU.

26 Confidentiality

26.1 All the stakeholders undertake to protect the secrecy of all the data of Beneficiary families and trade or business secrets of and will not share the same with any unauthorized person for any reason whatsoever within or without consideration.

26.2 The Provider agrees to protect the confidentiality under this agreement and ensures not to recruit ex-employees of MDIndia anytime during this agreement and also for a further period of one year from the date of expiry of this agreement.

27 Termination

27.1 Any deficiency in service by the empanelled hospitals (Provider) or noncompliance of the provisions of MOU will be scrutinized by the Empanelment & Disciplinary Committee (EDC) comprising of representative from the RGJAYS, Insurer and MDIndia and make deliberations to **suspend / de-list / stop payments** or any other appropriate action based on the nature of the complaint against the Provider. The Provider shall abide by the deliberations made by the EDC and RGJAY society.

27.2 If during the course of agreement any fraudulent claim is reported from the hospital, RGJAYS /Insurer / MDIndia has the right to terminate the hospital immediately from the network and payments of all the claims under consideration with MDIndia will stand forfeited. The final decision in this regard will rest with the EDC.

27.3 RGJAYS /Insurer /MDIndia reserve the right to terminate the agreement at any time on recommendation of EDC.

27.4 Either party can end the agreement with giving the notice of 90 days period with reasons properly clarified.

27.5 In case the Provider has any complaint against Insurer /MDIndia /RGJAYS /patient they have to report it to EDC for the resolution.

28 Jurisdiction:

28.1 This MOU shall be governed by the laws of India and any disputes between the parties with respect to the subject matter hereof shall be resolved by arbitration, pursuant to the provisions of the Arbitration and Conciliation Act, 1996, as amended, in the courts of Pune only.

28.2 The award of Arbitrator shall be binding on both the parties. In case, however the Arbitrators are unable to come to a conclusion then they may decide to appoint an umpire whose decision shall be final and binding on both the Parties.

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Medical Superintendent
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28.3 Neither party shall transfer its rights or obligations in any manner what so ever without the prior consent of the other

28.4 Any amendments in the clauses of the Agreements can effected as an addendum, after the written approval from both the parties.

29 Non-exclusivity

29.1 MDIndia/Insurer /RGJAYS reserves the right to appoint other Provider/s for implementing the packages envisaged herein and Provider will have no objection for the same and vice-versa.

30 REPRESENTATIONS AND WARRANTIES

Each party represents that:-

1. It has the power and authorization to enter into this MOU and perform its obligations hereunder and the Execution of this MOU does not violate or is consistent with its by-laws and other constituent documents.
2. The individuals signing this MOU on its behalf, whose name appears below, has the authorization to execute and deliver this MOU.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

By signing below each party agrees to the terms of this agreement.

PROVIDER:

Name of the Provider MGM Hospital Kamothe, Navi Mumbai

Through Shri/Smt/Dr. P. P. Doke (Authorized Signatory)

Sign

Date 14 Feb. 2012

In Presence of

Sign

SEAL OF THE HOSPITAL

MDINDIA:

Represented by Dr./Mr./Ms. RAJNISH SHARMA
MANAGING DIRECTOR
(Authorized Signatory)

Sign

Date:

In Presence of

Sign

SEAL OF MDINDIA

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

OUR CONTACT DETAILS

Authorisation department: Contact for assistance to utilize the cashless Facility.

1) Email Id: rgjayauth@mdindia.com
2) Toll free No: 1800 233 2222

Empanelment department:
Contact for any change in Provider information, Change in MCO, MCCO, up gradation of facilities

1) Email Id: pmrgjay@mdindia.com

2) Contact No.

Customer Care Department: For Cashless claim Inquiry

Toll free No: 1800 233 22 22

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

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M. G. M. HOSPITAL, KAMOTHE

Annexure A: IT Specifications

Sr. No.	Particulars	Qty	Specifications
1	Computer Set	1	1. CPU 1 x Intel Core i3-2100 CPU @ 3.10GHz (2790 MHz) 2. 2 GB DDR3 RAM 3. 250 GB Sata Hard Disk 4. Video RAM 1300 MB
2	Multi-Function Printer/Scanner	1	**1. Laser Printer** **2. Functions :** Print, Copy, Scan **3. Print speed black (normal, A4) Up to 18 ppm** **4. Scanner Specification :** **Scanner type:** Flatbed, ADF **Scan resolution:** optical Up to 1200 dpi **Bit depth :** 24-bit **Scan size (flatbed) :** maximum 216 x 297 mm **Scan size (ADF):** maximum 216 x 356 mm **Automatic document feeder capacity :** Standard, 35 sheets **5. Digital Sender Specifications :** Digital sending standard features : Scan to E-mail; scan to application; scan to file **6. Minimum system requirements:** Microsoft® Windows® 7, Windows Vista®, Windows® XP, Windows® Server 2003: 1 GHz processor, 1 GB RAM, 700 MB free hard disk space, SVGA 800 x 600 with 16-bit colour display, Internet Explorer 5.5 or higher, USB or Ethernet port **7. Compatible operating systems:** Microsoft® Windows® 7, Windows Vista®, Windows® XP, Windows® Server 2008, Windows® Server 2003; Mac OS X v 10.4, v 10.5, v 10.6; Linux
3	Barcode Scanner	1	Light Source Visible Laser Diode 650 nm + 10 nm Laser Power < 1.0 mW @ peak power Depth of Scan Field 0 mm - 140 mm (0" - 5.5") for 0.33 mm (13 mil) bar codes Width of Scan Field 49 mm (1.9") @ face; 195 mm (7.7") @ 140 mm (5.5") Scan Speed 72 scan lines per second Scan Pattern Single scan line Minimum Bar Width 0.102 mm (4.0 mil) Decode Capability Autodiscriminates all standard bar codes, including RSS; for other symbologies call Metrologic System Interfaces PC Keyboard Wedge, RS232, IBM 468x/469x, Stand Alone Keyboard, USB (low speed and full speed) Print Contrast 35% minimum reflectance difference Number Characters Read Up to 80 data characters Roll, Pitch, Yaw 42°, 68°, 52° Beeper Operation 7 tones or no beep Indicators (LED) Green = laser on, ready to scan; Red = good read

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Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

Sr. No.	Particulars	Qty	Specifications
4	Computer Multimedia Speaker	1	**Functions:** Power, Volume, Headphone Jack **Speaker Section :** 2 Speaker drivers Magnetically Shielded **Dimensions (W X H X D) :** 21.5 cm x 22cm x 9 cm (each satellite) **Frequency :** 100hz-20Khz **Output Power :** 460 Watts PMPO **Input Electric Voltage :** 230 V AC
5	Microphone	1	Computer microphone, very clear. Even in the relatively noisy environment can be better to eliminate the background sound.
6	USB Hub	1	1. Offers stackable, reversible design 2. Features four 480Mbps ports 3. Transfers your data at up to 480Mbps 4. Installs easily with Plug-and-Play convenience 6. Connect up to 2 high-speed devices without a power supply 7. Works seamlessly with all your USB 1.1 and USB 2.0 devices 8. Supports "hot swapping" of all your USB devices 9. Lets you monitor port and power status with LEDs System Requirements: For PC Users: Pentium® processor-based computer with USB 2.0 or USB 1.1 port available; Windows 98, 2000, ME, XP and Vista, Win 7
7	Web Camera	1	1. Image Sensor: High Quality 1/4" Cmos Sensor 2. Sensor Resolution: 480K pixels 3. Video Format: High quality 5G wide angle lens 4. Lens: 6 LEDs for night vision, with brightness controller 5. USB Interface: USB 2.0 backward compatible with USB Microphone 7. Still Image Resolution : 640x480, 800x600, 1024x768, 1280x960, 10280x1024, 1600x1200, 2304 x 1728 8. Valid pixels : 300k, 480k, 1.3m, 2.0M, 5.0M, & 8.0 m Pixels 9. Frame Rate: 300 frame rate per second 10. Adjustable focus: 5cm to Infinity 11. Automatic White Balance: Yes 12. Automatic Exposure: Yes 13. Automatic Compensation : Yes 14: Power Supply : USB bus powered 15 OS Support: Windows XP, Vista and & Win 7
8	Digital Camera	1	1. Sony Cyber-Shot 2. 14.1 Mega Pixels 3. 5x Optical Zoom 4. 28mm wide-angle lens (35mm format) 5. 7 LCD Screen 2.7"/ 6.7 cm 6. Sweep Panorama 7. 4Gb Memory Card 8. Mode Auto Intelligent

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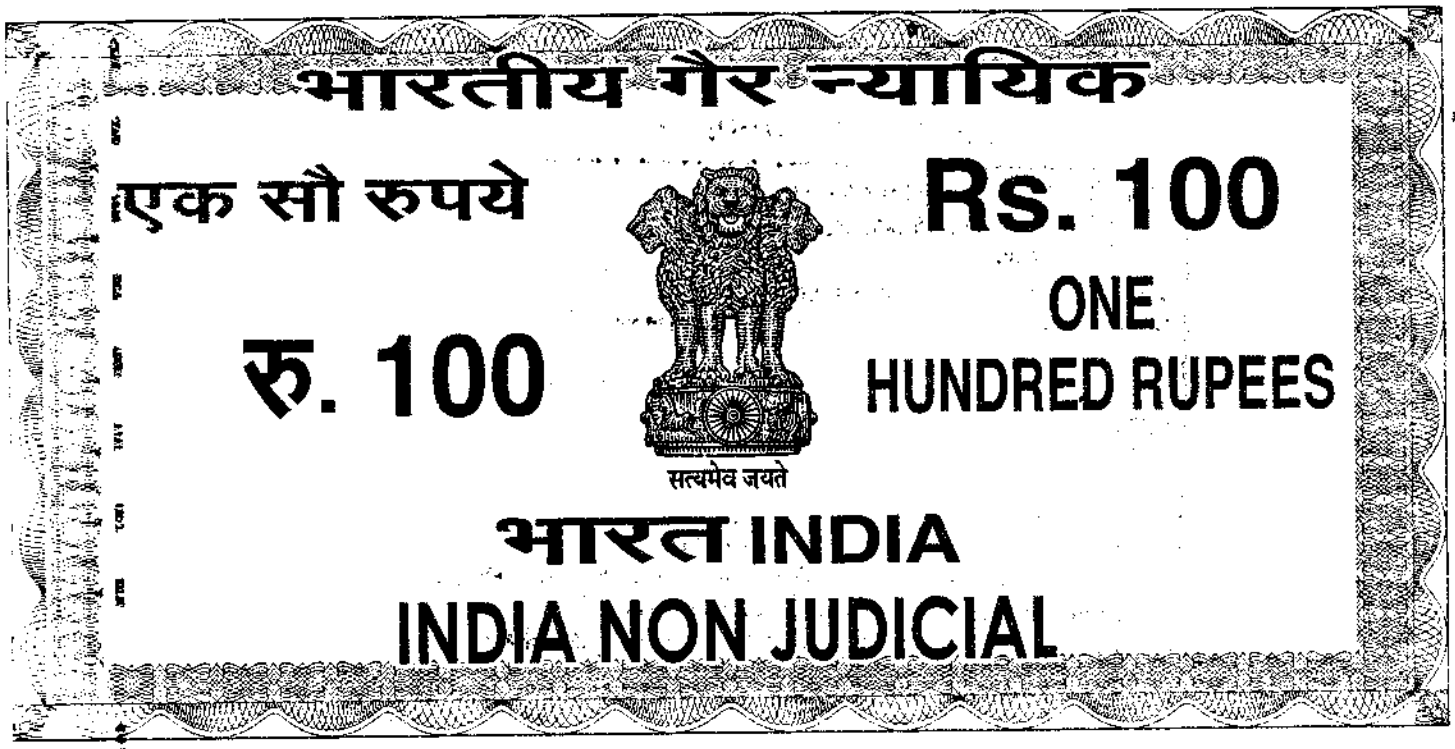
Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE



महाराष्ट्र MAHARASHTRA ◐ 2017 ◐ TB 444003

प्रधान मुद्रांक कार्यालय, मुंबई
एम.एच.क ८०००००९
19 JAN 2018
सक्षम अधिकारी

श्रीमती. एस. व्हि. मसूरकर

CLINICAL STUDY AGREEMENT

by and between

TATA MEMORIAL CENTRE
Main Building, 3rd Floor, IRB Department,
Dr. Ernest Borges Road, Parel, Mumbai - 400 012
Maharashtra, India, Tel: +91-22-24168601, Fax: +91-22-24154005

And

Institution
Mahatma Gandhi Mission's Medical College and Hospital,
N-6 Cidco, Aurangabad – 431003, Maharashtra, India,
Tel: +91-240-6601100, Fax: +91-240-2487727

परिशिष्ट-१/ANNEXURE - I

फक्त प्रतिज्ञापत्रासाठी / Only For Affidavit

मुद्रांक विक्री वाबतची नोंद वही अनु. क्र./दि.
(Serial No./Date)

मुद्रांक विकत घेणाऱ्याचे नाव व रहिवासी पत्ता
Stamp Purchaser's Name/place of Residence & Signature

परवानाधारक मुद्रांक विक्रेत्याची सही
JYOTI R. ROGA
LSV No. [illegible]
6, Kondaji Bldg. No. 3, Nr. Tata
Hospital, Parel, Mumbai - 400 012.

(शासकीय कार्यालयासमोर / न्यायालयासमोर प्रतिज्ञापत्र सादर करण्यासाठी मुद्रांक कागदाची आवश्यकता नाही. शासन आदेश दि. ०१/०७/२००४ नुसार)
ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

996 23 JAN 2018

परिशिष्ट-२ / ANNEXURE-II

मुद्रांक विक्री नोंद वही अनु. क्रमांक /दिनांक
(Serial No./Date)

दस्तऐवजाचा प्रकार /अनुच्छेद क्रमांक AGREEMENT
(Nature of Document)

दस्त नोंदणी करणार आहेत का?
(Whether it is to be Registered) Yes/No

मिळकतीचे थोडक्यात वर्णन
(Property Description in brief)

मुद्रांक विकत घेणाऱ्याचे नाव व सही Tata Memorial Centre
(Stamp Purchaser's Name & Signature)

हस्ते असल्यास त्यांचे नाव व पत्ता व सही
(If through other person then Name, Add & Signature)

दुसऱ्या पक्षकाराचे नाव MGM Medical College Aurangabad
(Name of the other party)

मुद्रांक शुल्क रक्कम
(Stamp Duty Amount)

परवानाधारक मुद्रांक विक्रेत्याची सही
JYOTI R. ROGA
LSV No. [illegible]
6, Kondaji Bldg. No.3, Nr. Tata
Hospital, Parel, Mumbai-400012.

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे

A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Clinical Study Agreement

And

Pricipal **Investigator**
Dr Navin Kasliwal
Mahatma Gandhi Mission's Medical College and Hospital
N-6 Cidco, Aurangabad – 431003
Maharashtra, India
Mob.-9370353555
Email - navinkasliwal@gmail.com

Study Name: A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Study Centre Code : 20
Principal Investigator : Dr. Navin Kasliwal
Confidentiality Agreement Date: 06/06/2016

Clinical Study Agreement (CSA) with Institution and Principal Investigator edition 3.1, IN
Template Active Date:

A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Clinical Study Agreement

TABLE OF CONTENTS PAGE

LIST OF APPENDICES

CLINICAL STUDY AGREEMENT

This CLINICAL STUDY AGREEMENT (the '**Agreement**') is made effective as of the last date of the signatures below (the 'Effective Date') by and between

Tata Memorial Centre, Dr. Ernest Borges Road, Parel, Mumbai - 400 012, Maharashtra, India (herein after referred to as "Study Coordinating Centre")

National Cancer Grid, having its office in the location of Tata Memorial Centre, Dr E Borges Road, Parel, Mumbai 400012, Maharashtra, India (herein after referred to as "Sponsor")

Mahatma Gandhi Mission's Medical college & hospital a legal entity with a facility at N-6 Cidco, Aurangabad, and represented by at Dr. Navin Kasliwal Assistant Professor (herein after referred to as "Site")

Dr. Navin Kasliwal, Assitant Proffesor. Surgery Departement. Mahatma Gandhi Mission's Medical college & hospital. Aurangabad (the "Principal Investigator")

Background

WHEREAS, National Cancer Grid, primarily funded by the Department of Atomic Energy, Government of India, has been constituted with the object, among others, of collaborative research in cancer with the institutions concerned, and having its office in the location of Tata Memorial Centre, Dr. E Borges Road, Parel, Mumbai 400012 intends to conduct a multi centre A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

WHEREAS, Tata Memorial Centre would be functioning in the role of Study Coordinating Centre on behalf of National Cancer Grid with respect to the said multi centre Clinical Trial of the Study;

WHEREAS, Institution has appropriate facilities and personnel necessary to conduct the Study; and

WHEREAS, Principal Investigator has the necessary qualifications, experience and expertise to conduct the Study, and has represented that he is agreeable to conduct the study relying on his own independent assessment.

A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Clinical Study Agreement

Agreement

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, the Parties agree as follows:

1 DEFINITIONS

Unless otherwise specifically provided in this Agreement, capitalized terms shall have the meaning set forth in Appendix A.

2 CONDUCT OF THE STUDY

2.1 The Site and Principal Investigator have agreed to conduct the Study. Sponsored by National Cancer Grid and the Tata Memorial Centre would be the Study Coordinating Centre on behalf of the Sponsor.

2.2 The Parties shall conduct the Study in accordance with this Agreement, the Protocol, and/or other prescribing information as each may be amended, and in compliance with all Applicable Laws and Requirements, any condition required by an IEC. Principal Investigator shall follow all guidelines and instructions reasonably provided by National Cancer Grid or the study coordinating centre.

2.3 Site and Principal Investigator, by signing this Agreement, acknowledge that they have been selected to conduct the Study because of their experience, expertise and resources.

3 PRINCIPAL INVESTIGATOR

3.1 Principal Investigator shall be responsible on a day-to-day basis for the conduct of the Study, including responsibility for training Study Site Staff and supervising their work.

3.2 Principal Investigator and/or Study Site Staff may be invited to attend and participate in Study Meetings. To the extent that Principal Investigator and/or Study Site Staff attend a Study Meeting, the Parties agree that there will be no additional compensation for attendance or participation at such Study meeting, and the Site will bear the expenses as per their rules.

3.3 National Cancer Grid intends to conduct Study meetings in compliance with the applicable laws, regulations and codices of India. Principal Investigator on behalf of itself and Study Site Staff acknowledge and confirm that their attendance at a Study meeting directly relates to their participation in the Study and is not an inducement.

3.4 When attending Study meetings Principal Investigator on behalf of itself and Study Site Staff represent and warrant that their attendance is authorized by their employer and will not cause them to be in non-compliance with or in breach of any policy, procedure or service regulations of the Institutional concerned.

3.5 Principal Investigator shall:

3.5.1. Prior to the commencement of the Study, provide to the Sponsor/Study Coordinating Centre with evidence of his/her qualifications through a current curriculum vitae and other relevant documentation related to his/her qualifications, and a list of

appropriately qualified Study Site Staff and, as applicable, their curriculum vitae. Such list shall be kept up to date during the Study;

3.5.2. Collaborate with other Principal Investigators via face to face meetings, telephone and email contacts;

3.5.3. Obtain all approvals from the relevant IEC(s) (including approval of the Informed Consent Materials) necessary to conduct the Study and keep National Cancer Grid and Study Coordinating Centre fully apprised on the progress of such submissions constitution of independent IECs and provide written documentation of such approval(s)

3.5.4. Maintain all approvals from the IEC(s), as may be required.

3.5.5. Ensure that any amendments (agreed in writing by the Parties) to a Protocol are approved by the relevant EC prior to implementation of such amendments;

3.5.6. Obtain prior consent of – Sponsor or the Study Coordinating Centre and IEC(s) prior approval to any advertisement in respect of the Study;

3.5.7. Use his/her best endeavours to enroll the target number of Subjects within the enrolment period as set forth in Article 8 and Appendix C;

3.5.8. Ensure that Informed Consent to participate in the Study is obtained from each Subject and maintained in accordance with the Study Protocol and documented in a form approved by National Cancer Grid/Study Coordinating Centre and the relevant IEC;

3.5.9. Ensure that no Subjects are enrolled in the Study before prior written approval has been given by Sponsor and/or Study Coordinating Centre;

3.5.10. Notify Sponsor and/or Study Coordinating Centre, Site and the relevant IEC of any serious adverse event that occurs during the course of the Study in accordance with the Protocol and Applicable Laws and requirements;

3.5.11. Ensure that all medical records of all Subjects are kept and maintained in accordance with Appendix C and CRF instructions;

3.5.12. Ensure that CRFs are completed within the agreed time period, as set out in Appendix C;

3.5.13. Allow and, if requested, be available at Study related monitoring, audits of Sponsor/Study Coordinating Centre , EC review, audit, and provide direct access to Study Documentation, Subject medical records and other source documents as soon as reasonably possible upon request by Sponsor and/or Study Coordinating Centre

3.5.14. Immediately notify Sponsor and/or Study Coordinating Centre if he/she is contacted by a Regulatory Authority with respect to the Study, and provide any response that pertains to Sponsor and/or Study Coordinating Centre for review and approval prior to submission;

3.5.15. Provide all reasonable assistance and cooperation as Sponsor and/or Study Coordinating Centre may request in connection with any regulatory matter relating to the Study;

3.5.16. Ensure that all Study Site Staff complies with the parts of this Agreement that relate to their duties in the Study;

4. INSTITUTION

4 Institution shall:

4.1.1 Obtain all approvals as may be necessary for the conduct of the study and ensure that such approvals may be necessary for the conduct of the study, and ensure that such approvals remain valid till completion and termination of the study by taking prompt and appropriate actions as may be necessary.

4.1.2. Ensure the performance of the obligations of Principal Investigator and Study Site Staff as set out in this Agreement;

4.1.3. Give Sponsor/Study Coordinator written notice at such time as it becomes aware that Principal Investigator plans to leave Site or shall be unable to complete the Study. Site shall, in consultation with Sponsor /Study Coordinator use reasonable endeavour's to promptly nominate a replacement for Principal Investigator, and with the approval of relevant ECs shall appoint a replacement for Principal Investigator

4.1.4. Allow and, if requested, be appropriately represented at Study related monitoring, of sponsor, Study Coordinating Centre, EC review, audits and provide direct access to Subject medical records and the Study Documentation as soon as reasonably possible upon request by Sponsor or its designee, or IEC;

4.1.5. Provide all reasonable assistance and cooperation as Sponsor and/or Study Coordinating Centre may request in connection with any regulatory matter relating to the Study;

4.1.6. Notify immediately Sponsor/Study Coordinating Centre if it is contacted by a Regulatory Authority with respect to the Study, unless prevented from doing so by Applicable Laws and Requirements, and provide any response to such Regulatory Authority that pertains to the Study to Sponsor/Study Coordinating Centre for review and approval prior to submission;

4.1.7. Make available adequate facilities, including the Study Site, equipment and any other resources that are reasonably required to safely follow the Protocol;

4.1.8. Retain and store complete, current, accurate, organized and legible Study Documentation in a manner acceptable for the collection of data for submission to, or review by EC and/or Sponsor, and in full compliance with the Protocol and all applicable Laws and Requirements, and for such time period as specified in Appendix C; and

4.1.9. Ensure that no Study Documentation is destroyed without the prior written approval of Sponsor.

5. TATA MEMORIAL CENTRE - NATIONAL CANCER GRID

The National Cancer Grid, primarily funded by the Department of Atomic Energy, Government of India, has been constituted with the object, among others, of collaborative research in cancer with the institutions concerned, and having its office in the location of Tata Memorial Centre, Dr E Borges Road, Parel, Mumbai 400012. intends to conduct a multi centre "A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer and the legal arm for the execution of the provisions of this Agreement rests with the Tata Memorial Centre, who will be the Study

Coordinating Centre, notwithstanding that it has not been so specifically provided in the applicable clauses of this Agreement

5.1.1. Assist site to obtain all approvals from the relevant EC or Regulatory Authorities necessary for the conduct of the Study;

5.1.2. Assist the duly appointed National Co-ordinating Investigator to collaboratively work with site Principal Investigators/Institutions to discuss study specific requirements;

5.1.3. Provide Site or Principal Investigator with all amounts for Investigational Product required for completion of the Study;

5.1.4. Provide Principal Investigator with all current and relevant information(s) regarding the Investigational Product;

5.1.5. Implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure the Study can be conducted and data generated, documented, recorded and reported in compliance with the Protocol and GCP and applicable laws;

5.1.6. Subject to Site's and Principal Investigator's obligations and responsibilities under this Agreement and Applicable Laws and Requirements, coordinate all safety and serious adverse event reporting to ECs and Licensing Authorities.

5.1.7. Agrees to promptly report any findings to the Institution/ Investigator that could affect the safety of participants or influence the conduct of the study

5.1.8. Agrees to promptly report Data and safety monitoring reports to the Institution/ Investigator

5.1.9 Subject to the prior approval of the Institution, TMC-NCG may use Institution and Investigator contact details for publication purpose.

5.2.0 Agree to communicate findings from a closed research study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (30 days) after closure of the study

5.2.1. Register the Study on clinical trials registries and publish the Study results in clinical results databases, as required by Applicable Laws and Requirements.

6 REPRESENTATIONS AND WARRANTIES

6.1 Site and Principal Investigator (to the extent that such representations and warranties relate to Principal Investigator) each represents and warrants to National Cancer Grid/Coordinating Centre

6.1.1. That they will make available adequate time, personnel, facilities and resources to efficiently and expeditiously accomplish its responsibilities under this Agreement, in particular to conduct the Study within the agreed time schedule and in the way set forth in the Protocol;

6.1.2. That none of Site\Principal Investigator or any member of the Study Site Staff, is subject to any conflicting obligations or legal impediments or has any financial or other interest in the outcome of the present Study or has entered into any contract with respect

to the present Study that might interfere with the performance of the present Study or that might impair the acceptance of the resulting data or the grant of rights to Sponsor hereunder or create a conflict of interest;

6.1.3. That they will promptly notify Sponsor of any potential conflicts of interest that exist or may arise in relation to the Study;

6.1.4. That Site and Study Site Staff, including Principal Investigator, are properly registered with appropriate registration bodies wherever is applicable and are sufficiently qualified by training and experience for conduct of the Study; and

6.1.5. Site is not currently using, and shall not use the services of any person, including Principal Investigator, who is debarred, proposed for debarment or otherwise disqualified or suspended from performing a clinical study or otherwise subject to any restrictions or sanctions by any Regulatory Authority and/or IEC with respect to the performance of scientific or clinical investigations. Institution will immediately notify Sponsor and Study Coordinating Centre, if it becomes aware of any such debarment, proposal for such debarment, disqualification or suspension.

6.1.6. That all the necessary approvals from the EC are in place and shall insure that they are received before commencement of the study

7. STUDY SITE

Institution and Principal Investigator shall conduct the Study at the Study Site identified in Appendix C, or such other Study Sites as the Parties may agree in writing.

8. SUBJECT ENROLMENT

8.1 Principal Investigator shall enroll Subjects to the Study in accordance with Appendix C. The Subject enrolment period may be extended or shortened and the number of Subjects that Institution and Principal Investigator may enroll in the Study may be changed, at Sponsor Study Coordinating Centre sole discretion.

8.2 Site and Principal Investigator acknowledges that this Study is part of a Multi-Centre Study and that when the enrolment goal for the Multi-Centre Study as a whole is reached, enrolment will be closed at all sites, including at Institution, regardless of whether Institution or any other site has reached its individual enrolment goal.

9. INVESTIGATIONAL PRODUCT

9.1 Investigational Product shall be used only for the Study and strictly in accordance with the Protocol and all Applicable Laws and Requirements.

9.2 Investigational Product shall be stored securely under lock and key under temperature control area with restricted access to the study team members only.

10. COMPENSATION

10.1 For the services to be rendered under this Agreement, Coordinating Centre on behalf of the Sponsor shall pay Site and Principal Investigator in accordance with the specification in Appendix B. The Parties acknowledge that the amounts to be paid by Study Coordinating

Centre under this Agreement are reasonable compensation, representing the fair market value, for the work performed by Institution, Principal Investigator and Study Site Staff and that neither of Site, Principal Investigator or Study Site Staff have received any other compensation or inducement in connection with this Agreement or their participation in the Study.

10.2 No compensation will be given to the participants for participation in the study; Study Coordinating Centre will pay the amount to Site to cover the expenses for the study related injuries as per Study Coordinating Centre's policy. Site shall present the bill for such reimbursements to Sponsor/Study Coordinating Centre and the payment will be done as per actual.

10.3 Any amounts paid by Study Coordinating Centre to Site and Principal Investigator under this Agreement for services that have not been performed or expenses that have not been incurred shall promptly be refunded to Study Coordinating Centre upon the expiration or termination of this Agreement or earlier at the request of Sponsor and/or Study Coordinating Centre.

10.4 All amounts payable by Study Coordinating Centre to Site and Principal Investigator pursuant to this Agreement shall not be reduced except to the extent of taxes to be deducted statutorily required by Applicable Laws and Requirements. Site alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Laws and Requirements to be paid by Tata Memorial Centre - National Cancer Grid) levied on account of or measured in whole or in part by reference to, any payments it receives. Study Coordinating Centre shall deduct or withhold from the amounts payable any taxes that it is required by Applicable Laws and Requirements to deduct or withhold.

10.5 All payments made by Study Coordinating Centre under this Agreement are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, Study Coordinating Centre shall pay such Indirect Taxes at the applicable rate in respect of any such payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by Institution in respect of those payments, such Indirect Taxes to be payable on the due date of the payment to which such Indirect Taxes relate.

11. INTELLECTUAL PROPERTY

11.1 The intellectual property rights of the study and information generated from the study will vest with the Study Coordinating Centre.

11.2 Site and Principal Investigator shall, and shall cause Study Site Staff to, make prompt and full disclosure to Study Coordinating Centre. The site and Principal Investigator agree that the individual (s) who conceived the idea (s) and the Study Coordinating Centre shall own all rights and title in and to all intellectual property. The site and Principal Investigator hereby assigns and transfers, and shall cause Study Site Staff to assign and transfer, without additional consideration, accordingly. It is agreed that the site will be granted a non-exclusive, perpetual royalty-free license, without the right to grant sub-licenses, to use any and all such intellectual property for strictly internal research and/or educational purposes and/or patient care purposes. provided that the restrictions with regard to Confidential Information and Publication in Articles 12 and 14 are observed and adhered to.

11.3 Upon the request and at the sole expense and exclusive control of / Study Coordinating Centre. The site and Principal Investigator shall, and shall cause Study Site Staff to, apply for cooperation with Study Coordinating Centre(or its designee) in executing and delivering any

and all instruments necessary or reasonably useful to enable Study Coordinating Centre(or its designee) to apply for patents (and to obtain any patent term extension, supplementary protection certificate, divisional, validation, reissue, continuance or renewal) or like privilege or any other protection on any of the Study Coordinating Centre/individual concerned on which intellectual property right is vested as aforesaid, anywhere in the world, as they may in their discretion determine the site and Principal Investigator shall, and shall cause Study Site Staff to, execute or cause to be executed, all papers necessary to effect the foregoing, including assignments to Study Coordinating Centre/the individual concerned, as necessary or useful to vest all rights without additional consideration.

11.4 Each Party shall retain all rights in its respective Background Intellectual Property. This Agreement is not intended to and shall not infer any license grant or assignment, whether expressed or implied, with regard to such Background Intellectual Property. Notwithstanding the foregoing, Site and, to the extent applicable Principal Investigator, hereby grants to the Study Coordinating Centre/the individual(s) who conceived the idea(s) a perpetual, worldwide, non-exclusive, royalty-free license, with the right to grant sub-licenses, to use Site's Background Intellectual Property and Principal Investigator's Background Intellectual Property to the extent required to use for research purposes.

12. CONFIDENTIAL INFORMATION

12.1 At all times during the term of this Agreement and for a period of ten (10) years following termination or expiration thereof, each Party (the 'Receiving Party') shall, and shall cause its officers, directors and other employees and agents to, keep confidential and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information provided to it by the other Party (the 'Disclosing Party'), except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. Any data and information referable to the intellectual property shall be deemed as Confidential Information of Study Coordinating Centre irrespective of where such data and information was developed or generated. Upon the termination or expiration of this Agreement or upon a Party's earlier request, the Parties shall promptly return to the other Party all of its respective Confidential Information, provided that each Party shall have the right to retain, subject to the other provisions of this Section 12.1, a copy of any Study Documentation to the extent required by Applicable Laws and Requirements.

12.2 The obligations of confidentiality in shall not extend to any Confidential Information that (a) is or comes into the public domain without breach of this Agreement, (b) is received by Receiving Party from a third party without any obligation of confidentiality and without breach of this Agreement, or (c) Receiving Party can prove was already in its possession without any limitation on use or disclosure prior to the Effective Date or (d) information (s) those are required to be disclose under obligation to the Govt Authorities, under any law, sanction or by any court order etc of such nature.

12.3 The Parties agree to maintain the Confidential Information in a secure facility, taking commercially reasonable steps to protect the information from unauthorized use, access and disclosure.

13. PERSONAL DATA AND BIOLOGICAL MATERIALS

13.1 Each Party shall be responsible for its own processing of Personal Data and shall ensure that any Personal Data relating to a Subject, Principal Investigator and/or Study Site Staff, is collected, stored, used, disclosed and transferred in accordance with all applicable privacy

laws and with the Informed Consents that are or will be obtained from Subjects. Principal Investigator shall be responsible for obtaining and providing Study Coordinating Centre with written consent (in the prescribed form) from each Study Site Staff for the collection, use and disclosure of their Personal Data.

13.2 Each Party shall ensure that any collection, handling, transportation and retention of Biological Materials, is carried out in accordance and in compliance of, with the Protocol, Informed Consent and all Applicable Laws and Requirements. Site and Principal Investigator agree and acknowledge that Sponsor/Study Coordinating Centre may use the Biological Materials to conduct Secondary Research, subject to the Informed Consent and in accordance with Applicable Laws and Requirements.

13.3 Each Party shall ensure that the security, integrity and quality of the Biological Materials are maintained at all times. Each Party shall be responsible for maintaining its own chain of custody to allow traceability and management of the Biological Materials.

13.4The ownership of the biological materials will vest with the Sponsor/Study Coordinating Centre

14. PUBLICATION AND USE OF STUDY RESULTS

14.1 Sponsor is committed to communicate product, research and development information in an accurate and objective fashion. These communication activities must be undertaken in a responsible and ethical manner, taking into account relevant external standards regarding the manner and content of scientific, technical and medical publications. The sponsor's Publication Policy, Appendix D, describes its commitment to data disclosure and transparency and how the sponsor/ Study Coordinating Centre will work with external investigators and authors to develop publications from research collaborations. The International Committee of Medical Journal Editors (ICMJE) authorship guidelines will be followed.

14.2 In the exercise of the rights of academic freedom, Site and Principal Investigator (but no other Study Site Staff) shall, not withstanding Article 12 above but subject to this Article 14, have the right to publish the Study results in scientific or other journals, or to present the Study results at professional conferences or other meetings, subject to the following restrictions.. As the study is multi centre study, Site and Principal Investigator shall not publish or present any such results until the earlier of (i) the date of the first Multi-Centre Results publication, authorized by Sponsor/ Study Coordinating Centre and (ii) the end of the eighteen 18) month period following the completion, or early termination, of the Study at all participating sites. Neither before nor after such date may Site or Principal Investigator publish or present any raw data (as distinguished from the results of any analyses of raw data) or make any publication or presentation that is false, misleading, and inconsistent with academic standards or for commercial purposes.

14.3 Sponsor and Study Coordinating Centre shall have the right to independently publish the Study results, subject to Article 15 and provided that due acknowledgement is made for the intellectual contribution made by Site and Principal Investigator in accordance with standard scientific practice.

14.4 Without limitation to any other right of Sponsor and/or Study Coordinating Centre Site and Principal Investigator acknowledge and agree that Sponsor will register the Study and, when available, post the Study results in accordance with Study Coordinating Centre's internal policy on one or more publicly-accessible trial registries and websites (including the government-funded website http://www.clinicaltrials.gov). Site and Principal Investigator should not undertake registration or posting of results to avoid duplication of entries. The

Sponsor/Study Coordinating Centre's personnel must comply with local/national law and/or regulations which require registration of study information to a publicly-accessible registry other than those named above. Where Site and Principal Investigator wish to use a publicly-accessible website on a voluntary basis (eg. a university/hospital website) the information related to the Protocol must not exceed the information Sponsor/Study Coordinating Centre has already posted and it should be sufficient to provide a hyperlink to the trial when registered onhttp://www.clinicaltrials.gov/

15. USE OF NAME

None of Site, Principal Investigator or Sponsor/Study Coordinating Centre shall mention or otherwise use the name, trademark, trade name or logo of the other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party; provided, however, that Sponsor shall have the right to identify Institution as the site at which the Study was conducted and the responsible Study Site Staff, and to use Principal Investigator's name in any Sponsor/Study Coordinating Centre's recruitment activities.

16. INSURANCE AND INDEMNITY

16.1.Sponsor agrees to maintain the insurance of suitable amount and to indemnify Site and Principal Investigator and hold them harmless in respect of and against all claims and proceedings made or brought by or on behalf of Subjects in accordance with Law, against Site or Principal Investigator for personal injury to Subjects, to the extent arising out of or relating to (i) the administration of Investigational Product in accordance with this Agreement, the Protocol and any other written instructions of Sponsor/Study Coordinating Centre or (ii) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, provided that, in each case:

16.1.1. Site and Principal Investigator have followed the instructions of Sponsor/ Study Coordinating Centre and complied with the Protocol (and any amendments thereto) and Applicable Laws and requirements; and

16.1.2. Site and Principal Investigator have used reasonable medical judgment in the conduct of the Study (including the enrolment of Subjects for which participation in the Study is medically appropriate).

16.2. The Sponsor/Study Coordinating Centre obligation to indemnify under Section 16.1 will not apply to the extent that such claims or proceedings:

16.2.1. Arise out of or relate to the negligence, wilful misconduct or wrongful act or omission of Institution, Principal Investigator or any Study Site Staff;

16.2.2. Arise out of or relate to Principal Investigator's or site's failure to report promptly to sponsor/Study Coordinating Centre any significant or alarming development that has occurred during the Study, including any Subject adverse event or serious adverse event (as both such terms are defined in the Protocol);

Or 16.2.3. Arise as a result of Site's or Principal Investigator's compromise or settlement of any such claim without the written consent of Sponsor/Study Coordinating Centre.

16.3 Institution accepts responsibility to compensate Sponsor/ Study Coordinating Centre for any and all losses caused by:

16.3.1. The negligence or wilful misconduct of Site, Principal Investigator or Study Site Staff in performing their obligations under this Agreement; or

16.3.2. The failure of Site, Principal Investigator or Study Site Staff, to comply with the provisions of this Agreement, the Protocol, any written instructions of Sponsors/Study Coordinating Centre concerning the Study or any Applicable Laws and Requirements.

16.4 The Study Coordinating Centre maintains liability insurance in respect of its obligations to third parties and maintains sufficient limits to cover the indemnification obligations in this agreement.

16.5 Site confirms that it shall maintain liability insurance in amounts sufficient to cover its obligations set forth in this Agreement and produce evidence thereof, if and when so requested by the Sponsor/Study Coordinating Centre.

17. TERM AND TERMINATION

17.1 This Agreement commences on the Effective Date and will remain in effect until the final data has been provided to Sponsor/Study Coordinating Centre or earlier termination of this Agreement in accordance with this Article 17.

17.2 Either Party may terminate this Agreement at any time upon written notice if the other Party is:

17.2.1. In breach of any obligations under the Agreement or the Protocol (including a failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of cure, within fifteen (15) days of written notice from the other Party specifying the breach and requiring its cure; or

17.2.2. Declared insolvent or has an administrator or receiver appointed over all or parts of its assets or cease or threatens to cease to carry on its business.

17.3 Any Party may terminate this Agreement with immediate effect upon written notice to the other Party, if it on reasonable grounds believes the Study should cease in the interest of the health, safety or well-being of Subjects.

17.4 Sponsor/Study Coordinating Centre may terminate this Agreement upon notice to Site if Principal Investigator is no longer able (for whatever reason) to act as principal investigator of the Study and no replacement mutually acceptable to the parties has been found.

17.5 In addition to Sections 17.2, 17.3 and 17.4 above, Sponsor/Study Coordinating Centre may terminate or suspend the Study and/or terminate this Agreement immediately for any reason whatsoever upon written notice to Site and Principal Investigator.

17.6 In the event of termination of this Agreement by either of the Parties, the Parties shall use their best efforts to minimize any inconvenience or harm to any Subjects in the Study.

17.7 Upon notice of termination of this Agreement, Site and Principal Investigator shall immediately cease enrolment of Subjects into the Study, and promptly provide to Sponsor Study Coordinating Centre all Study Documentation (except such documents as are required to be maintained by Site pursuant to Applicable Laws and Requirements), and Sponsor Study Coordinating Centre's Confidential Information in connection with the Study

and provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study with no disruption of the Protocol.

17.8 Upon expiration or early termination of this Agreement (except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by Institution) Study Coordinating Centre shall, upon receipt of invoices and other supporting documentation, pay to Site and Principal Investigator all costs incurred and falling due for payment up to the date of termination and all non-cancellable costs committed before receipt of notice of termination, provided that such commitments are reasonable and necessarily incurred by Site or Principal Investigator for the performance of the Study prior to the date of termination and agreed with Sponsor/Study Coordinating Centre.

17.9 Within thirty (30) days after the termination of this Agreement, the Principal Investigator and Site shall deliver to Sponsor/Study Coordinating Centre in writing a final accounting of:

17.9.1. All Subjects that participated in the Study;

17.9.2. The Subject visits completed in accordance with the Protocol during the term of this Agreement; and

17.9.3. All reasonable direct costs incurred in connection with any transfer of the Study.

18. INDEPENDENT CONTRACTOR

In undertaking to perform its, his or her respective services hereunder, Site, Principal Investigator and Study Site Staff are doing so as independent contractors in relation to Sponsor/Study Coordinating Centre and not as their employees or agents.

19. GOVERNING LAW AND JURISDICTION

The interpretation and construction of this Agreement and the rights and obligations of the Parties hereunder shall be governed by the laws of India, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. If any party is delayed or prevented from the performance of any act required under the Agreement by reason of any act of god, act of nature, including any academic or outbreak of pandemic disease, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining raw material, energy or other supplies, labor disputes of whatever nature or whatever reason beyond the control of the party, performance of such act shall be excused for the period of such event provided that if such interference lasts for any period in excess of thirty (30) days each party may, by written notice to others, modify this agreement.

Any dispute, controversy or claim arising out of or relating to this agreement which cannot be resolved within thirty (30) days by mutual consent of the parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by sole arbitrator if the parties do agree. In the event no agreement could be arrived on the appointment of sole arbitrator, each party will nominate an arbitrator each, who will appoint an umpire before proceeding with the arbitration. The place of arbitration shall be Mumbai .

The award of the arbitrator shall be final and binding on both parties. The parties bind themselves to carry out the awards of the arbitrator. The section shall survive termination or expiration of this Agreement. The cost of arbitration shall be incurred by both the parties

equally. The cost in Mumbai will have exclusive jurisdiction to adjudicate the disputes or differences between the parties, referred to it

20. NOTICES

Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or by facsimile (with receipt of transmission confirmed by the receiving Party), addressed to the Parties at their respective addresses set forth in the preamble to this Agreement, or at such other address such Party may have provided to the other Party in accordance with this Article 21. Such notice shall be deemed to have been given as of the date delivered. Any notice delivered by facsimile shall be followed by a hard copy delivered as soon as practicable thereafter. This Article 21 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this agreement.

21. SURVIVAL

The respective rights and obligations of the Parties set forth in Articles 6, 9, 11, 12, 13, 14, 16, 19, 22 and 23 and Sections 11.2, 11.3, 11.4, shall survive the expiration or termination of this Agreement to the extent necessary to preserve such rights and obligations.

22. ENTIRE AGREEMENT AND AMENDMENT

22.1 This Agreement together with the Appendices hereto and the Confidentiality Agreement constitute the entire agreement among the Parties hereto with respect to the subject matter of this Agreement and supersede all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.

22.2 Institution hereby authorizes Principal Investigator to, on its behalf; agree on amendments or modifications of Appendix C without prior approval of Institution.

23. INCONSISTENCY

In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects (including Article 14), the terms of this Agreement shall prevail. In the event of inconsistency between this Agreement and the Confidentiality Agreement, the Confidentiality Agreement shall prevail only regarding confidential information not covered by this Agreement.

24. COUNTERPARTS

This Agreement may be executed in two or more counterpart copies, each of which shall be deemed an original, and shall together be deemed to constitute one and the same instrument.

A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Clinical Study Agreement

Execution

THIS AGREEMENT IS EXECUTED by the authorized representatives of Sponsor and Site and Principal Investigator as of the dates indicated below.

SIGNED for and on behalf of National Cancer Grid

Name: Dr R A Badwe

Title:

Date: 29th Jan 2018

SIGNED for and on behalf of Mahatma Gandhi mission's medical college & Hospital

Name: Dr. Rajendra Bohra

Title: Dean

Date:

Signed By Principal Investigator

Name: Dr. Navin Kasliwal.

Title: Principal Investigator

Date:

Appendix A: Definitions

'Applicable Laws and Requirements' means all applicable laws, rules and regulations, including, without limitation, Regulatory Authority rules and guidelines relating to the conduct of the Study, including GCP (as defined below).

'Test Drug' means the Tata Memorial Centre - National Cancer Grid medicinal product being studied or tested in the Study, including any placebo.

'Test Drug Invention' means all inventions relating to the Tata Memorial Centre - National Cancer Grid Test Drug including, without limitation, new indications or uses thereof, that are conceived, generated or otherwise made by Institution, Principal Investigator or any Study Site Staff (other than Tata Memorial Centre - National Cancer Grid) whether solely or jointly with others, under or in connection with the Study. For the avoidance of doubt, Tata Memorial Centre - National Cancer Grid Test Drug Inventions also include any inventions relating (a) to the Tata Memorial Centre - National Cancer Grid Test Drug's metabolic activity, pharmacological activity, side effects, drug metabolism, mechanism of action, safety, or drug interactions, or (b) to biomarkers, assays, diagnostic methods or diagnostic products, which may be used to predict patient response or resistance to the Tata Memorial Centre - National Cancer Grid Test Drug or be used in any way to select patients for treatment with the Tata Memorial Centre - National Cancer Grid Test Drug.

'Background Intellectual Property' means any Intellectual Property that was owned or controlled, directly or indirectly, by a Party prior to the Effective Date.

'Biological Materials' means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells.

'Case Report Form' or **'CRF'** means a printed document ('p-CRF'), optical or electronic document ('e-CRF') or database designed to record all of the information, to be reported to Tata Memorial Centre - National Cancer Grid on each Study Subject, as required by the Protocol.

'Confidential Information' means any data and information related to the terms of this Agreement, the Study (including the Test Drug and Study Documentation), any Background Intellectual Property, Tata Memorial Centre - National Cancer Grid Intellectual Property and Institution Intellectual Property, that is provided by either Party or otherwise developed or generated in connection with the discussions and negotiations pertaining to, or in the course of performing, this Agreement.

'Confidentiality Agreement' or **'CDA'** means the confidentiality agreement entered into by and between Institution and/or Principal Investigator and Tata Memorial Centre - National Cancer Grid relating to the Study on the date set forth on the cover of this Agreement.

'Good Clinical Practice' or **'GCP'** shall have the meaning defined by the ICH Harmonised Tripartite Guideline for Good Clinical Practice, at all times in its most recent version.

'Independent Ethics Committee' or **'IEC'** means an independent body, institutional, regional, national or supranational committee or review board, whose responsibility it is to ensure the protection of rights, safety and well-being of human subjects in a clinical study and responsible for, among other things, reviewing and approving/providing opinion on, the Protocol, the suitability of the investigator(s), facilities, subject recruitment materials, methods and Informed Consent Materials.

'Indirect Taxes' means value added taxes ('VAT'), sales taxes or similar taxes.

'Informed Consent' has the meaning set forth by GCP.

Clinical Study Agreement

'Informed Consent Materials' means the information to be provided to potential Subjects in the Study to secure their Informed Consent, including information about any compensation being provided to Subjects for their participation in the Study.

'Institution' means Institution including all employees, Study Site Staff, executives, officers, directors, and agents of Institution.

'Institution IP' means all Intellectual Property other thdan the Tata Memorial Centre - National Cancer Grid IP that is conceived, generated or otherwise made by Institution, Principal Investigator or any Study Site Staff (other than Tata Memorial Centre - National Cancer Grid) under or in connection with the Study.

'Intellectual Property' means any and all rights in and to ideas, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

'Investigational Product' means the Tata Memorial Centre - National Cancer Grid Test Drug, which is to be administered in the study according to the protocol.

'Materials' means any equipment, materials (excluding Investigational Product), documents, data, software and information supplied by or on behalf of, or purchased at the expense of, Tata Memorial Centre - National Cancer Grid, in connection with the Study.

'Multi-Centre Study' means a study conducted by several investigators according to a single protocol at more than one study site.

'Party' means each of Tata Memorial Centre - National Cancer Grid, Institution and Principal Investigator, and

'Parties' means Tata Memorial Centre - National Cancer Grid, Institution and Principal Investigator collectively.

'Personal Data' means any information and data that is directly or indirectly referable to a natural person who is alive.

'Principal Investigator' means the person identified on the cover of this Agreement appointed to lead and co-ordinate the Study on behalf of Institution, or any other person as may be agreed by the Parties as a replacement.

'Protocol 'means the clinical study protocol identified by the study code on the cover of this Agreement, which describes the Study, including all amendments thereto as the Parties may from time to time agree in writing.

'Site Closure' means the date of receipt by Principal Investigator of the site closure visit report from Tata Memorial Centre - National Cancer Grid.

'Study 'means the clinical study described in the Protocol.

'Study Documentation' means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

Clinical Study Agreement

'Study Meeting' means meetings regarding the Study to which Principal Investigator and/or Study Site Staff is invited by or on behalf of Tata Memorial Centre - National Cancer Grid, including, but not limited to, investigator, study coordinator and/or results meetings.

'Study Site' means the facilities set out in Article 6.

'Study Site Staff 'mean all those students, employees, agents or others who are engaged by Institution or Principal Investigator in the conduct of the Study, including any sub-investigator.

'Subject' means a person recruited to participate in the Study.

Clinical Study Agreement

Appendix B Payment

National Cancer Grid (Sponsor) shall compensate Institution and Principal Investigator for each Subject that completes the Study in accordance with the Protocol. For Subjects who are withdrawn before the end of the Study, compensation will be provided on a pro-rata basis on completion of visits as follows from the specification below. No financial compensation will be given for Subjects, who, within Principal Investigator's control, are incorrectly included according to the inclusion and/or exclusion criteria or lost to follow-up. The same applies for Subjects for whom the primary variable cannot be evaluated.

Sponsor/ Study Coordinating Centre shall have the right, in its own discretion, to make deductions from the compensation set forth in this Appendix for any and all material and major Protocol deviations.

1. Per Subject Payment	**In INR**
Randomization, drug administration and HPR	Rs. 700/-
First Follow Up (After completion of adjuvant treatment)	Rs. 1000/-
Subsequent follow ups (Minimum 2 follow up per year for 5 dsyears)	Rs. 1000 per year for 2 follow up visits (will be given for 9 follow up)
Additional payment for SAE's	On actual – Management and Hospitalization cost for all study treatment related SAE's
2. Additional Compensation	
Study Coordinator fees	Rs.12000/- pm (for site randomizing minimum 4 patients per month)
Research Fellow fees	Rs.25000/- pm (for site randomizing minimum 10 patients per month)
Ethics Committee fees	As per Actuals
Administrative charges (Including study medication i.e. Inj. Hydroxyprogesterone)	Rs. 300/-
Follow up visit charges (yearly after 5 years)	Rs. 1500/-

Clinical Study Agreement

3. Payment Terms	
Payments will be made to:	MGM Medical College, Aurangabad
Account details:	Account / Payee Name: **MGM Medical College, Aurangabad** PAN No.: **AAATM4256E** A/C NO- **0376104000000107** IFSC code: **IBKL0000376** Bank Name: **IDBI Bank**
Invoices will be sent to Tata Memorial Centre at:	Tata Memorial Hospital Main Building 3rd Floor, CRS Department, Dr. Ernest Borges Road, Parel, Mumbai 400012

A Phase III Randomized Controlled study of Inj. Proluton (Hydroxyprogesterone caproate) as single dose preoperative therapy in patients with high risk operable breast cancer

Clinical Study Agreement

Appendix C Facilities, Records and Resources

In addition to the duties described in the Master Agreement, the Principal investigator shall:

- Promptly provide Sponsor/ Study Coordinator Centre with reports on any change significantly affecting the conduct of the study or putting the subjects at increased risk. For changes in staff and/or responsibilities.
- In addition, written reports should be promptly provided to the Ethics Committee when any significant changes affect the conduct of the study or the risk to the subjects, when requested and at study completion.
- Ensure adequate workspace is provided for the monitor to conduct his/her monitoring activities.

1. PLANNED SUBJECT ENROLMENT

Study Site: Tata Memorial Hospital, Mumbai.

Number of Enrolled Subjects:

Number of Randomised subjects:

First Subject Enrolled by:

Last Subject Completed before:

Planned Subject Enrolment Annex:

As per Table 1 below

Table 1 Planned Subject Enrolment Annex

Month	Planned Enrolment	Planned Randomised
February – December 2016		
January - December 2017		

*Planned enrolment and randomised patient recruitment figures should be entered. Timings are currently planned and may be subject to change.

Institution acknowledges that the Study is part of a Multi-Centre Study, and agrees that when the enrolment goal for the Multi-Centre Study as a whole is reached, enrolment will be closed at all sites, including Institution, regardless of whether Institution or any other site has reached its individual enrolment goal."

2. MATERIALS PROVIDED BY TATA MEMORIAL CENTRE - NATIONAL CANCER GRID

Tata Memorial Centre - National Cancer Grid will supply/lend the following documents/equipment, which may be retained/should be returned at the end of the study:

Study Protocol
Informed Consent Forms
Case Report Forms

4. SOURCE DATA, RECORDS AND STORAGE

4.1 Data Capture:

Data for each Subject should be entered in the Case Report Form within 3 working days of each completed visit respectively. Data queries shall be responded to within 3 working days of the query being raised. Please be advised that in preparation for IDMC meetings and during the database lock period these timelines will be reduced.

4.2. Records and Documents

4.2.1. Medical Records

The medical (hospital/practice) records for each Subject should contain information which is important for the Subject. Safety and continued care and to fulfill the requirement that critical Study data should be verifiable. To achieve this, the medical records of each Subject should clearly describe at least:

- That the Subject is participating in the Study, e.g. by including the enrolment and/or the randomisation code and the Study code or other Study identification;
- Date when Informed Consent was obtained;
- Diseases (past and current; both the disease studied and others, as relevant);
- Treatments withdrawn/withheld due to participation in the Study;
- Treatments given, including Investigational Product, changes in treatments during the Study, and the time points for the changes.
- Visits to the clinic during the Study, including those for Study purposes only;
- Serious Adverse Events (if any) including causality assessments;
- Date of and reason for discontinuation; and
- Additional information according to local regulations and practice.

4.2.2. *Case Report Form as Source Document*

The following variables may be directly recorded in the CRF and need not be present in subject medical records (source document)

- Ethnic group
- Investigators signature
- Investigator aware date of SAE

4.3. **Storage of Study Documents**

The Study Documentation shall be retained and stored during the Study and for 3 years after Site Closure.

The Investigator's Study File must be retained at the Study Site per regulatory obligations and thereafter destroyed only after agreement with Tata Memorial Centre - National Cancer Grid. It can be stored either at the Study Site, or at a location agreed upon by Tata Memorial Centre - National Cancer Grid.

Appendix D Tata Memorial Centre - National Cancer Grid Publication Policy

TATA MEMORIAL CENTRE - NATIONAL CANCER GRID POLICY FOR SCIENTIFIC, TECHNICAL &MEDICAL PUBLICATIONS

Policy Sponsors: Dr. R A Badwe

Tata Memorial Centre - National Cancer Grid,

Dr. E Borges Road,

Parel, Mumbai, Maharashtra, India 400012

Issue Date: February 2013

Review Date: March 2013

1. Overview

Tata Memorial Centre - National Cancer Grid is committed to communicate information on its products and research in an accurate and objective fashion. These communication activities must be undertaken in a responsible and ethical manner. Patient safety is our primary concern, and therefore, paramount consideration is given to ensure that all relevant information is communicated clearly and in a timely way.

2. Scope

The Tata Memorial Centre - National Cancer Grid Policy for Scientific, Technical & Medical Publications covers all scientific, technical and medical publications originated or sponsored by Tata Memorial Centre - National Cancer Grid. When entering into research and development collaborations, Tata Memorial Centre - National Cancer Grids commitment to transparency, openness, and ethical publication will be communicated to these external partners as appropriate.

3. Publications from Research Sponsored by Tata Memorial Centre - National Cancer Grid

Tata Memorial Centre - National Cancer Grid is committed to publishing medically important results, whether positive or negative, from its clinical research in peer-reviewed journals. Tata Memorial Centre - National Cancer Grid seeks to ensure that publications in biomedical journals follow the guidelines established by the International Committee of Medical Journal Editors (ICMJE) and published in its Uniform Requirements of Manuscripts Submitted to Biomedical Journals (http://www.icmje.org). Importantly, these guidelines require recognition in the manuscript that the research was conducted in accordance with the Ethical Principles for Medical Research Involving Human Subjects (http://www.wma.net/en/30publications/10policies/b3/index.html) otherwise known as the Declaration of Helsinki. Tata Memorial Centre - National Cancer Grid also follows the principles outlined in the Good Publication Practice Guidelines (GPP2) (http://www.gpp-guidelines.org).

Clinical Study Agreement

4.1 **Access to Data**

To protect intellectual property effectively, any collaboration between Tata Memorial Centre - National Cancer Grid and a third party will be subject to a formal agreement that will address ownership and access to data. Tata Memorial Centre - National Cancer Grid will be responsible for ensuring that a complete database is compiled for all clinical studies sponsored by Tata Memorial Centre - National Cancer Grid.

4.2 Authorship

Tata Memorial Centre - National Cancer Grid is committed to ensuring that authorship for all publications complies with the criteria defined by the ICMJE. These state that: 'Each author should have participated sufficiently in the work to take public responsibility for the content.' Authorship credit should be based on 1) substantial contributions to acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet all 3 conditions. Each author must give his/her approval to have his/her name included in the list of authors. Tata Memorial Centre - National Cancer Grid believes that participation solely in the collection of data or drafting the manuscript does not justify authorship. These conditions apply equally to external investigators and to Tata Memorial Centre - National Cancer Grid employees.

In line with GPP2, Tata Memorial Centre - National Cancer Grid does not pay honoraria to investigators for authorship of peer-reviewed articles or presentations. http://www.gpp-guidelines.org.

4.3Financial Disclosure

Tata Memorial Centre - National Cancer Grid fully supports openness and transparency and hence the need for all authors of publications (both Tata Memorial Centre - National Cancer Grid employees and external collaborators) to disclose any potential conflicts of interest including any financial or personal relationships that might be perceived to bias their work.

5. Privacy

Tata Memorial Centre - National Cancer Grid respects the privacy of the relationship between patients and healthcare professionals and is committed to ensuring that the process of scientific publication does not breach patient confidentiality. Identifying information (eg, patient initials, personal code number, and hospital codes) will not be published unless the patient grants informed consent.

"B"

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Dear Ms Munjal,

Thank you for your reminder and please excuse this delayed reply.

It is to be noted that, due to budgetary constraints, the print runs have been decreasing significantly therefore affecting the number of copies distributed free of charge.

We are pleased to add the Central Medical Library of MGM Institute of Health Sciences in Navi Mumai, to our network of Reference Libraries for WHO publications, as it is confirmed that their collection will be accessible by the general public. There are no other conditions linked with that designation.

The Library will receive the Bulletin of the WHO, the World Health Report, and also nonserial publication and titles in the Technical Report series when sufficient stocks are available. A set of publications issued since the beginning of 2012 will be provided to the Library, free of charge.

If you have any questions or need further information, please let me know.

Thank you and best regards,

Marie-Pierre Austin
WHO Press (WHP)
World Health Organization
1211 Genève 27
Switzerland
Fax (4122) 791 4857
e.mail: austinm@who.int
Website: www.who.int
Catalogue on website: http://bookorders.who.int

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act)
Navi Mumbai- 410 209

Ms. Deepti [mailto:Adlakhad@searo.who.int] 2019/8/12 15:55

ECR/1083/MGM-ECRHS/Inst/MH/2014/Re-Registration-2017

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

सत्यमेव जयते

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 27/04/2018

To

The Chairman
MGM Ethics Committee for Research on Human Subjects (MGM-ECRHS)
Pharmacology Department, MGM Medical College, N-6, CIDCO
Aurangabad- 431003, Maharashtra
India

Sub:- Ethics Committee Re-Registration No. **ECR/581/Inst/MH/2014/RR-17** issued under Rule 122DD of the Drugs & Cosmetics Rules, 1945.

Sir/Madam,

Please refer to your application submitted to this Directorate for the Re-Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby re-registers the **MGM ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MGM-ECRHS)** situated at **PHARMACOLOGY DEPARTMENT, MGM MEDICAL COLLEGE, N-6, CIDCO, AURANGABAD- 431003, MAHARASHTRA, INDIA** with Re-Registration Number **ECR/581/Inst/MH/2014/RR-17** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. The re-registration shall be in force from 11.09.2017 to 10.09.2020, unless it is sooner suspended or cancelled.
2. This registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
3. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
4. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
5. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
6. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
7. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
8. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.
9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    I. Basic medical scientist (preferably clinical pharmacologist)
    II. Clinician
    III. Legal expert
    IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person
    V. Lay person from community

14. The members representing medical scientist and clinicians should have Post Graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and re-registration is sought for Institutional Ethics Committee.

19. Funding mechanism for the Ethics Committee to support their operations should be designed to ensure that the committee and their members have no financial incentive to approve or reject particular studies.

20. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.

22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco- regional and community settings similar to that of the registered Ethics committee. The approving ethics committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.

23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (4) mentioned above.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (I) & Licensing Authority
स्वास्थ्य सेवा महानिदेशालय

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's
ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS
MGM campus, N-6, CIDCO, Aurangabad - 431003
Ph. No.: 0240-6601100, 6601174, Fax No.: +91-0240-2487727
Email: mgmecrhs@gmail.com

Office: Dr. Deepak Bhosle, Prof & Head dept of Pharmacology & MGM-ECRHS, MGM Medical College, Aurangabad-431003.

DATE:-29-03-18

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairman:-Dr.Manvendra Sawalaram Kachole,Jawaharlal Nehru engineering College,Aurangabad.

2. Name and address of the office of Ethics Committee*MGM Ethics Committee for Research on Human Subjects(MGM-ECRHS),Pharmacology Department,MGM Medical College,Aurangabad-431003,Maharashtra.

3. Names, address, qualifications & designation of the other members of the Ethics Committee.*

Sr. No.	Name of the member	Qualification with Specialization	Name of the Organization with complete address	Telephone number/Fax number/E-mail/Residential address	Designation (Chairman/ Member Secretary/ Member) of the Ethics Committee	Affiliation of member with institute (Institute constituted the Ethics Committee)
1	Dr.Manvendra Kachole	M.Sc. Ph.D	Jawaharlal Nehru engineering College, Aurangabad.	0240-2323094 mskachole@yahoo.com	Chairman	Professor, Bioinformatics Department, Jawaharlal Nehru engineering College, Aurangabad.
2	Dr.Deepali Jaybhaye Associate Professor	MBBS,MD	MGM Medical College Aurangabad	9423330726 deepalijaybhaye@rediffmail.com	Member Secretary	Associate Professor,Department of Pharmacology,MGM Medical College,Aurangabad.
3	Dr.A.G.Shroff Professor ,Department of Anatomy	MBBS,MD	MGM Medical College Aurangabad	0240-6601100 mgmecrhs@gmail.com	Basic Medical Scientist	Professor & Head Department of Anatomy, MGM Medical College,Aurangabad
4	Dr.S.H.Talib Prof & Head Dept of Medicine	MBBS,MD	MGM Medical College Aurangabad	0240-6601100 sftalib@gmail.com	Clinician	Professor & Head Department of Medicine,MGM Medical College,Aurangabad.
5	Dr.Sonali Bhattu Associate Professor Medicine Department	MBBS,MD	MGM Medical College Aurangabad	9970182314 0240-6601100 sonalibhattu@rediffmail.com	Clinician	Associate Professor Medicine Department, MGM Medical College,Aurangabad.
6	Dr.P.R.Suryawanshi Prof & Head Dept. of Surgery	MBBS,MD	MGM Medical College Aurangabad	0240-6601100 Drspravin22@gmail.com	Clinician	Professor & Head Department of Surgery,MGM Medical College,Aurangabad.
7	Dr.S.M. Mahajan Associate Professor Dept. of PSM	MBBS,MD	MGM Medical College Aurangabad	0240-6601100 Deoswati@yahoo.co.in	Epidemiologist	Associate Professor Department of PSM,MGM Medical College,Aurangabad.

Dr. Rajesh B. Goel
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(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

8	Dr.Prashant Chaudhary Assistant Professor Dept. of Pharmacology	MBBS,MD	MGM Medical College Aurangabad	9405484850,0240-6601100 drprashantmgm@gmail.com	Clinical Pharmacologist	Assistant Professor Dept. of Pharmacology MGM medical College Aurangabad.
9	Dr.Rajesh Dase Associate Professor Dept. of PSM	M.Sc., Ph.D	MGM Medical College Aurangabad	9921100065,0240660 1100 Rdase25@gmail.com	Biostatician	Associate Professor Dept. of PSM, MGM Medical college,Aurangabad.
10	Adv.R.P.Mane Legal Adviser	BA,LLB,DLL, DBM	MGM Medical College Aurangabad	0240-6601100 mgmecrhs@gmail.com	Legal Expert	Legal Adviser, MGM Medical College,Aurangabad
11	Mr.Sewalikar	B.Com	Shivaji Nagar,Aurangabad.	9270983448 sanjaysewalikar@gmail.com	Social Scientist	Social Scientist
12	Mr.Mangesh V. Shinde	M.Ed	46,Sumta Nagar ,Kranti Chowk police Station road,Aurangabad	9423393821 Shindemangesh1974@gmail.com	Lay Person	Lay Person Extension officer Panchayat samiti,ZP,Aurangabad.

*** Indicate if there is any change in address &composition of the Ethics Committee.**

* If yes, provide the complete details i.e. new address and date of change & qualification, experience, and training of the new members as per the requirement of Drugs & Cosmetics Rules.

Commitments:

(i) The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well- being of the trial subjects.

(ii) In the case of any serious adverse event occurring to the clinical trial subj ects during the clinical trial, the Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.

(iii) The Committee shall allow inspectors or officials authorised by the Central Drugs Standard Control Organisation to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.

(iv) We agree to maintain adequate and accurate records after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

Chairperson
(Signature of the Chairman)
MGM-ECRHS
MGM's Medical College, Aurangabad

Member Secretary
(Signature of the Member secretary)
MGM-ECRHS
MGM's Medical College, Aurangabad
Date: 29/3/18

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

File No. EC/18/000006

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 28-Sep-2018

To

The Chairman
MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI
MGM Medical College, Navi Mumbai
Sector 1, Kamothe Navi Mumbai Panvel Raigad
Maharashtra - 410209 India

Subject: Ethics Committee Registration No. ECR/1133/Inst/MH/2018 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2017/1645 dated 29-Jan-2018 submitted to this Directorate for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI situated at MGM Medical College, Navi Mumbai Sector 1, Kamothe Navi Mumbai Panvel Raigad Maharashtra - 410209 with Registration number ECR/1133/Inst/MH/2018 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.

2. The Ethics Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.

3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.

4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.

5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled. Provided that if the application for re-registration is received by the Licensing Authority within three months before the expiry, the registration shall continue to be in force until orders are passed by the said authority.

a. The Licensing Authority shall be informed in writing in case of any change in the membership or the constitution of the Ethics Committee takes place.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution, Besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

I. Basic medical scientist (preferably one pharmacologist)
II. Clinician
III. Legal expert
IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
V. Lay person from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.

19. Funding mechanisms for the Ethics Committee to support their operations should be designed to ensure that the committees and their members have no financial incentive to approve or reject particular studies.

20. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

21. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained as long as required.

22. Ethics Committee may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, subject to the condition that the other sites are within the loco-

regional and community settings similar to that of the registered Ethics committee. The approving Ethics Committee must be willing to accept their responsibilities for the study at such trial site(s) and the trial site(s) willing to accept such an arrangement.

23. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial. The ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts where required, for deciding relatedness and compensation, as per condition no (3) mentioned above.

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
Date: 2018.10.04 10:26:09

(S. Eswara Reddy)
Drugs Controller General (I) &
Licensing Authority

File No. EC/18/000006

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 28-Sep-2018

To

The Chairman
MGM INSTITUTIONAL ETHICS COMMITTEE NAVI MUMBAI
MGM Medical College, Navi Mumbai
Sector 1, Kamothe Navi Mumbai Panvel Raigad
Maharashtra - 410209 India

Subject: Ethics Committee Registration No. ECR/1133/Inst/MH/2018 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2017/1645 dated 29-Jan-2018 submitted to this Directorate for the Registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No.ECR/1133/Inst/MH/2018 with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Jaishree Ravindra Ghanekar	MBBS (MD - Medicine)	Clinician
2	Dr. Anant Dattatray Urhekar	MBBS (MD - Pathology & Microbiology)	Basic Medical Scientist
3	Dr. D Bhusare	MBBS (MS - General Surgery)	Clinician
4	Ms. Usha Mohite	10th (Not Applicable)	Lay Person
5	Dr. Pramila Yadav	MBBS (MD-Pharmacology)	Chair Person
6	Dr. Pradeep R Jadhav	MBBS (MD-Pharmacology)	Member Secretary
7	Dr. Ipseeta S Ray	BSc (MSc.,PhD-Pharmacology)	Scientific Member
8	Dr. Ravindra Shriniwas Inamdar	MBBS (MD-Physiology)	Basic Medical Scientist
9	Dr. Rajeev S Chaudhary	MBBS (MD- Forensic Medicine)	Basic Medical Scientist
10	Ms. Rupali V Gujar	BA (MSW)	Social Scientist
11	Ms. Karuna Ramraje Malviya	LLB (LLM)	Legal Expert

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
Date: 2018.10.04 10:05:05 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (I) &
Licensing Authority

भारत सरकार
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
पशु कल्याण प्रभाग
पशुओं पर परीक्षण के नियंत्रण एवं पर्यवेक्षण के प्रयोजनार्थ समिति (सीपीसीएसईए)
Government of India
Ministry of Environment, Forest and Climate Change
Animal Welfare Division
Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)

F. No. 25/127/2010-AWD
02/05/2018

To

Dr. Savita Shahani, Chairperson IAEC,
Mahatma Gandhi Mission's Medical College,
Sector - 18, Kamothe, Navi Mumbai - 410209, Maharashtra,
Mobile: 9819277578
E-mail: drshahanirediffmail@yahoo.co.in

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Subject: Revision of Institutional Animals Ethics Committee (IAEC) – regarding

Madam,

Kindly refer to your application on the above subject. CPCSEA hereby accords approval to your request for revision of IAEC.

2. Accordingly, the revised IAEC is as under:

S.No.	Name of IAEC Members	Designation in IAEC
1.	Dr. Savita Shahani	Biological Scientist(Chairperson)
2.	Dr. Ipseeta Ray	Scientist from different biological discipline(Member Secretary)
3.	Dr. R S Inamdar	Scientist from different biological discipline
4.	Dr. G S Narshetty	Scientist Incharge of Animal House Facility
5.	Dr. Mohan Latkar	Veterinarian
6.	Dr. Uddhav Kalu Chaudhari	Main Nominee
7.	Dr. Vikas D. Dighe	Link Nominee
8.	Dr. Dhanjit Kumar Das	Scientist from outside the Institute
9.	Prof. Vishnu N. Thakare	Socially Aware Nominee

Contd..

3. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC mettings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six(6), and CPCSEA Nominees must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailablity in writing to the chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a Calendar year. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

4. The above composition of IAEC is valid upto the renewed period of registration i.e. 18.01.2022.

Yours faithfully,

(S. P. Singh)
Under Secretary (CPCSEA)

Copy for information to Nominees of CPCSEA:

1. Dr. Uddhav Kalu Chaudhari- Main Nominee
2. Dr. Vikas D. Dighe- Link Nominee
3. Dr. Dhanjit Kumar Das- Scientist from outside the Institute
4. Prof. Vishnu N. Thakare- Socially Aware Nominee

Print

F. No. 25/30/2014-CPCSEA

Government of India
Ministry of Environment, Forest & Climate Change
Animal Welfare Division
O/o Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
******

5th Floor, Vayu Block, Indira Paryavaran Bhawan,
Jor Bagh Road, New Delhi - 110003
28/08/2017

To

Dr. Jyoti Bobde, Chairperson, IAEC
MGM Medical College
N-6, CIDCO, Aurangabad - 431003, Maharashtra
Email:jyobobde@gmail.com
Mobile:9423781558

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC)-regarding

Madam,

The registration of Animal House Facility of your establishment with CPCSEA has been renewed **for a period of five years from the date of issue of this letter.**

- The new registration number of Animal House Facility of your establishment is ***1777/PO/Re/S/14/CPCSEA for Research for Education purpose of small animals***. Henceforth, the new registration number may kindly be quoted in all your future correspondence with this office.
- The CPCSEA has accepted the following members recommended by the establishment:

S.No.	Name of the IAEC Members	Designation in IAEC
1	Dr. Sangita Phatale	Scientist from different discipline, Member Secretary
2	Dr. Vishvesh Bansal	Scientist from different discipline
3	Dr. Rajendra suryavanshi	Veterinarian

4	Dr. Sambhaji Shinde	Biological Scientist
5	Dr. Jyoti Bobde	Scientist Incharge of Animal House Facility, Chairperson

- CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

S.No.	Name	Nominated as
1	**Dr. Shrikant B. Satale** Flat No. 2, Sairaj Apartment, Plot 15, Sandesh Nagar, Garkheda, Aurangabad, Maharashtra - 431009 Contact No :09730459199 Email :drshrikantsatale@gmail.com	Main Nominee
2	**Dr. Aman B. Upaganlawar** Associate Professor, Deptt of Pharmacology, SNJB's SSDJ College of Pharmacy, Jain Gurukul, Neminagar, Chandwad – 423 101, Nashik, MS Contact No :0956033551 Email :amanrx@yahoo.com	Link Nominee
3	**Dr. Chandrashekhar Upasani** Row House NO. 7, 'Tejas', Kashika Nagar, Bhujbal Farm, Mumbai-Agra Road, Nashik - 423009, Maharashtra Contact No :9822112007 Email :cdupasani@rediffmail.com	Scientist from outside the Institute
4	**Dr. Jaykumar S. Satav** Shree Bhagirathi Residency, Flat No. B-1, Near Zambad Estate, Shahanoormiya Darga, Railway Gate, Aurangabad Contact No :9423124827 Email :jaykumarsatav@gmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

- The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

- You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

- **It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and CPCSEA Nominees must be present in such meetings .Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC.Socially aware member's presence is compulsory in cases referred to CPCSEA and atleast in one meeting in a calendar year.Any decision taken in the meetings of IAEC without quorum shall be considered invalid.**

- It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours faithfully,

(S. Gowri Shankar)

Deputy Secretary (AW) & Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

The Main Nominee is requested to conduct the Inspection of Animal House Facility within a period of 30 days and submit the Inspection Report on the Website of CPCSEA.