

for Clinical Trial, Bioavailability and Bioequivalence Study and Relating to Biomedical and Health Research (BHR).

Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India. Established - 6th January 1987

Registered by:

Recognized by:

Central Licensing Authority with Re-Registration No.ECR/229/Inst./MH/2013/RR-19 issued Under New Drug and Clinical Trials

Rules, 2019. Valid from April 22, 2019 thru April 21, 2024 and Government of India, Ministry of Health & Family Welfare,

Department of Health Research, File No. - EC/NEW/INST/2019/202, Provisional certificate dated 12-OCT-2019. Western Pacific Region (FERCAP) for its compliance with international and local standards in ethical review.

Valid from Nov 20, 2016 thru Nov 19, 2020.

Accredited by:

NABH: National Accreditation Board for Hospitals & Healthcare Providers (Constituent Board of Quality Council of India).

Valid from May 19, 2018 thru May 18, 2021 Certificate No. EC-CT- 2018-0027

### Annual report as on 31st December 2020 INSTITUTIONAL ETHICS COMMITTEE (IEC) I, II & III

Established: 1987

Reigstration / Accreditation /	IEC-I	IEC-II	IEC-III
Recognition  Govt of India, DGHS, CDSCO DCGI & Licensing Authority: Drugs Controller General (India)	Re-Registration No. ECR/229/Inst./MH/2013/ RR-19 Valid from 22.04.2019 to 21.04.2024	Re-Registration No. ECR/417/Inst./MH/2013 /RR-19 Valid from 06.08.2019 to 05.08.2024	-
Govt of India, Ministry of Health & Family Welfare, Dept of Health Research (DHR)	Provisionally approved on 12 <sup>th</sup> Oct 2020 File no. – EC/NEW/INST/2019/202	Provisionally approved on 12 <sup>th</sup> Oct 2020 File no. – EC/NEW/INST/2019/ 200	Provisionally approved on 12 <sup>th</sup> Oct 2020 File no. – EC/NEW/INST/2019/ 203
SIDCER &FERCAP:Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Forum for Ethical committees in Asia and theWestern Pacific Region (FERCAP) for its compliance with international and localstandards in ethical review.	Awarded on Nov 20, 2016	Awarded on Nov 20, 2016	-
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Current SOPs Version 6.1, Dated 29th June 2020 effective from 1st August 2020

Both committees presently functions according to the requirements laid down in DCI, New Drugs and clinical trials rules, 2019 (NDCTR), and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.

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### **Activities of the IECs**

### 1) Total meetings of IECs held in the year 2020

IEC	;- I	IEC	- II	IEC	C- III	537	AE nmittee	Total me	eetings	TOTAL
1/1/2020 to 21/03/2020	During pandemic	1/1/2020 to 21/03/2020	During pandemic	1/1/202 0 to 21/03/2 020	During pandemi c	1/1/2020 to 21/03/202 0	During pandemic	1/1/2020 to 21/03/20 20	During pande mic	
2	12	3	7	2	5	7	23	14	48	61

### 2) Total initial projects reviewed by IECs

	IEC	C- I	IEC	;- II	IEC	-	То	tal	TOTAL
	1/1/2020 to 21/03/2020	During pandemic	1/1/2020 to 21/03/2020	During pandemic	1/1/2020 to 21/03/2020	During pandemic	1/1/2020 to 21/03/2020	During pandemic	
Pharma	2	16	-	-	-	-	2	16	16
GOVT	-	8	3	10	-	-	3	18	21
Other Academic(OA)	-	5	32	42	26	71	58	118	176
Thesis	2	1	31	42	38	30	71	73	144
TOTAL	4	30	66	94	64	101	134	225	359

### 3) Active projects as on 30th Dec 2020

		2010	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total	TOTAL
	PHARMA	-	1	2	-	-	-	3	7	9	4	26	
	GOVT	-	-	-	-	-	-	-	-	-	5	5	33
IEC-I	OA	-	-	-	-	-	-	-	-	-	1	1	
	Thesis	-	-	-	-	-	-	-	1	-	-	1	
	GOVT	1	-	-	1	-	4	-	7	5	6	24	
IEC-II	OA	-	-	1	-	9	15	14	46	41	32	158	513
	Thesis	-	-	-	-	-	35	57	113	102	24	331	
	PHARMA	-	-	-	-	-	-	-	-	-	-	-	
	GOVT	-	-	-	-	-	2	-	4	3	12	9	456
IEC-III	OA	1	1	3	1	1	9	8	39	47	38	148	
	Thesis	-	-	-	-	-	32	49	121	85	12	299	
TOTAL		2	2	6	2	10	97	131	338	292	122	1002	1002

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### 4) Projects are in process (queries sent to investigators)

		2017	2018	2019	2020	Total	TOTAL
	PHARMA	-	-	6	9	15	
	GOVT	1	-	-	1	2	25
IEC-I	OA	-	-	-	5	5	25
	Thesis	-	-	2	1	3	
	GOVT	-	=	1	4	5	
IEC-II	OA	-	4	18	39	61	110
	Thesis	-	4	15	25	44	
	GOVT	-	1	-	-	1	
IEC-III	OA	-	4	12	50	66	118
	Thesis	-	5	9	37	51	
TOTAL		1	18	63	171	253	253

### 5) Review performed by IECs in year 2020

				Dur	ing 1/1/20	20 to 21/03	/2020			
			IEC-I			IEC-II		IE	C-III	Total
Review	PH	OA	Govt	Thesis	OA	Govt	Thesis	OA	Thesis	
Full Board	2	-	-	2	23	3	31	22	38	121
Expedited	-	-	-	-	6	-	-	2	-	8
Exemption	-	-	-	-	3	-	_	2	-	5
Total	2	-	-	2	32	3	31	26	38	134
			4			66	-1		64	134

					During	pandemic	•			
			IEC-I			IEC-II		IE	C-III	Total
Review	PH	OA	Govt	Thesis	OA	Govt	Thesis	OA	Thesis	
Full Board	16	5	8	1	19	8	42	36	30	165
Expedited	-	-	-	-	17	2	_	31	N=	50
Exemption	-	-	-		6	-	-	4	-	10
Total	16	5	8	1	42	10	42	71	30	225
			30			94		1	101	225



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### 6) Serious Adverse Events reported and reviewed in the year 2020:

	Particulars			PHARMA	GOVT	OA	THESIS
1	Total no. of SAE	Initial r	eport	14	8	-	-
	at our site:	Follow	up report	19	4	-	-
		causal	ity	-	-	-	-
2	Total no. of death			-	2		-
3	Our site late repor	ting (aft	er 24 hours)	1	-		-
4	Responses (query	) from	Query letters sent	34	8	-	-
	EC regarding ou SAEs	ır site	Noted letters sent	42	6	-	_
7	Total no. of Advers	se Even	ts (AE) reported	15	-	-	-
8	Total no. of SUSA	R/CIOM	IS reported:	6923	-	7-	-

### 7) IECs Composition:

#### Member list of IEC-I as on 18th December 2020

Sr. No.	Name	Education Qualification with Specialization	Current Organization (Name and address)	Designation/ Role of member Ethics Committee	Affiliation of member with institute
1.	Dr. Mrs. Padmavathy Menon	M.D., Medicine DM. Endocrinology	Jupiter Hospital, Eastern Express Highway, Service Rd, Next to Viviana Mall, Thane, Maharashtra 400601.	Chairperson	No
2.	Dr. Mrs. Yashashri Shetty	M.D., DBM. Associate Professor (Pharmacology & Therapeutics)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member Secretary (Basic Medical Scientist)	Yes
3.	Dr. Mrs. Urmila Thatte	M.D., DNB., Ph.D. Emeritus Professor (Clinical Pharmacology)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Basic Medical Scientist)	Yes
4	Mrs. Dr. Charulata Londhe	M. D. (Internal Medicine) Associated Professor (Medicine)	Lokmanya Tilak Municipal Medical College and General Hospital, Sion, Mumbai. 400 022.	Member (Clinician)	No

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5.	Ms. Veena Johari	L.L.B.	Independent Lawyer	Member Legal Expert	No
6.	Ms. Meera Shah	M.S.W (Social Work) M. A. (Clinical Psychology) N.L.P., R.E.T. and Counseling	-	Member Social Scientist	No
7.	Dr. Mrs. Sai Kulkarni	M.A, PhD in Economics.	-	Member (Lay person)	No
8.	Dr. Bhaskar Krishnamurthy	D.M.(Pharmacology) M.D.(Pharmacology, Assistant Professor (Clinical Pharmacology)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Basic medical scientist)	Yes
9.	Dr. Sandeep Bavdekar	MD (Pediatrics), Diploma in Child Health, Certificate in Hospital & Diploma in Uniformation Technology (DIT)	Consultant & Chief Academics, Surya Children Hospital, Surya Children Medicare Pvt. Ltd. 101-102, Mangal Aashirvad SV Road, Santacruz (W), Mumbai 400054.	Member (Clinician)	No
10.	Dr. Mrs. Sanjeevani Zadkar	MBBS, MD Associate Professor (Anesthesiology)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Clinician)	Yes
11.	Dr. Kaizad Damania.	M. D., DNB., F.C.P.S., D.G.O., D.F.P. Professor (Obstetrics & Gynaecology)	N.Wadia Maternity Hospital Parel, Mumbai 400012.	Member (Clinician)	No
12.	Dr.Milind Tullu	MD, DNB Pediatrics, DCH FCPS (Child Health), MNAMS (Member of National Academy of Medical Sciences), & FIAP (Fellow of Indian Academy of Pediatrics), Professor (Additional) Pediatrics)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Clinician)	Yes

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13.	Dr. Monty Khajanchi	DNB (Surgery), MBBS Assistant Professor (General Surgery).	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Clinician)	Yes
14.	Dr. Dheeraj Kumar	DM, DNB (Cardiology), Assistant Professor (Cardiology)	Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012.	Member (Clinician)	Yes

#### Member list of IEC-II as on 18th December 2020

Sr. No.	Name	Position on IEC-I	Affiliation	Designation	Qualification	Gen der
1.	Dr. Subodh Sirur	Chairperson	Non-Affiliated	Consultant, Dermatology Wockhardt Hospital, Mumbai Central, Mumbai	MBBS, DVD, LLM	М
2.	Dr. Alka Subramaniyam	Co- Chairperson (Clinician)	Non-Affiliated	Associate Professor (Psychiatry) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., D.N.B., DHA.	F
3.	Mrs. Palsule Shilpshree	Member Secretary	Affiliated	Assistant Professor (occupational Therapy) Seth GS Medical College and KEM Hospital Mumbai. Mumbai.	M.Sc OT	F
4.	Dr. Sharmila Jalgaonkar	Joint- Member Secretary (Basic medical scientist)	Affiliated	Associate Professor (Pharmacology &Therapeutics) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
5.	Dr. Swapna Kanade	Member (Clinician)	Affiliated	Associate Professor, (Microbiology) Seth GS Medical College and KEM Hospital Mumbai.	MD	F
6.	Dr. Smrati Bajpai	Member (Clinician)	Affiliated	Assistant Professor (Medicine) Seth GS Medical College and KEM Hospital Mumbai.	M.D., DNB	F

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7.	Dr. Pradnya Talawdekar	Member (Legal Expert)	Non-Affiliated	Independent Lawyer/ Project Manager, Ojus Medical Institute, The Tulip Star, Juhu Tara Road Juhu, Mumbai.	B.A.M.S., L.L.M.	F
8.	Dr. Nilesh Thakre	Member (Social scientist)	Non-Affiliated	Assistant Professor, Psychology, SNDT Women's University, Mumbai.	Ph.D. Psychology, M.A (Industrial &Business Psychology), M.I.R.P.M., M.A.(Clinical Psychology), N.E.T in Psychology, PGDICP., Dip TD.	M
9.	Dr. Sai Kulkarni	Member (Lay person)	Non-Affiliated	-	B.A., D.C.A., PGDEM, M.E.M./ PhD, M.A	F
10.	Dr. Sona Dave	Member (scientific expert) (Clinician)	Non-Affiliated	Professor, (Anaesthesiology) TNMC & BYL Nair Charitable Hospital, Mumbai.	M.D., DA., DNB	F
11.	Dr. Priyanka Honavar	Member (Clinician)	Affiliated	Assistant Professor (Obstetrics & Gynaecology) Seth GS Medical College and KEM Hospital Mumbai	DGO,DNB (OBGYN), FMAS	F
12.	Dr. Sandeep Sonone	Member (Clinician)	Affiliated	Associate Professor (Orthopaedics) Seth GS Medical College and KEM Hospital Mumbai.	MS,DNB.	М



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#### Member list of IEC-III as on 18th December 2020

Sr. No.	Name	Position on IEC-I	Affiliation	Designation	Qualification	Gende r
1.	Dr. Leena V Gangolli	Chairperson (External)	Non- Affiliated	Member of National Task Force for Palliative Care.	M.B.B.S., M.H.A. (T.I.S.S.), M.P.H.(Harvar duniversity) L.L.M.	F
2.	Dr. Sushma Save	Co-Chairperson (External)	Non- Affiliated	Associate Professor, Dept of Pediatrics, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital.	MD, DCH, IBCLC (USA).	F
3.	Dr. Amey Rojekar	Member Secretary	Affiliated	Assistant Professor (Pathology) Seth GS Medical College and KEM Hospital Mumbai.	M.D., D.N.B.	М
4.	Dr. Snehalata Gajbhiye	Joint- Member Secretary (Basic medical scientist)	Affiliated	Assistant Professor (Pharmacology & Therapeutics)Seth GS Medical College and KEM Hospital Mumbai.	M.D., FICS.	F
5.	Dr. Kavita Joshi	Member (Clinician)	Affiliated	Associate Professor of Medicine, Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F
6.	Dr. Melita Vaz	Member (External Social Scientist)	Non- Affiliated	-	PhD MSW MA	F
7.	Dr. Sai Kulkarni	Member (Lay person) External	Non- Affiliated	-	Ph.D., M.A,	F
8.	Mrs. Jaimala Shetye	(Member)	Affiliated	Associate Professor (Physiotherapy) Seth GS Medical College and KEM Hospital Mumbai.	MPTh	F
9.	Dr. Kranti Kadam	Member (Clinician)	Affiliated	Additional Professor (Psychiatry) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	F

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10.	Dr. Suchin Dhamnaskar	Member (Clinician)	Affiliated	Associate Professor, Dept. of General Surgery, Seth GS Medical College and KEM Hospital Mumbai.	M.S	М
11.	Dr. Vijaya M. Babre	Member(Clinician)	Non- Affiliated	Assistant Professor in Department of OBGY at K.J. Somaiya Medical College Sion Mumbai.	MBBS,DNB,FI COG,FCPS,DG O,DFP,DHA (Diploma of Hospital Administration)	F
12.	Dr. Prerana Shah	Member (Clinician)	Affiliated	Professor (Additional) Dept of Anaesthesia Seth GS Medical College and KEM Hospital Mumbai	M.D.	F
13.	Dr. Yuvaraj B. Chavan	Member(Clinician)	Affiliated	Professor (Additional) (PSM) Seth GS Medical College and KEM Hospital Mumbai.	M.D.	M

### 8) IEC office bearers:

	Name	Designation	Name of the IEC	Contact details
1.	Ms. Janhavi Katkar	General Manager	IEC	Tel: 24122188,
	(nayanvkatkar@gmail.com)			24107515,
2.	Ms. Manali Naik	Deputy Manager	IEC-I	Ext. no. 7515
3.	Ms. Shweta Surve	Deputy Manager	IEC-I	Email:
4.	Ms. PrajaktaAuti	Deputy Manager	IEC-III, SAE Subcommittee	iec-1@kem.edu
5.	Ms. Manasi Lad	Sr. Executive Assistant	IEC-II	iec-2@kem.edu
6.	Ms. Rasika Nikharange	Executive Assistant	IEC-II	iec-3@kem.edu
7.	Ms. Sneha Bhogle	Executive Assistant	IEC-III	-
8.	Mr. Pranay Toraskar	Executive Assistant	IEC-II	-
9.	Mr. Mangesh Khochade	Office Assistant	IEC	-

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### 9) Activities of the IEC

### 1. Training programs attended by IEC members and IEC staff:

- 1. IEC has organised NDCTR and Site Monitoring workshop on 31st October 2020 online via Google Meet. All Three IEC's members attended the workshop.
- 2. Dr. Bhaskar Krishnamurthy attended: 7th National Conference of Forum for Ethics Review Committees in India (FERCICON) 2020 from 27th to 29th November 2020 online via Google Meet organized by Experimental Pharmacology laboratory (EPL), Department of Pharmacology, PGIMER.
- 3. Dr. Bhaskar Krishnamurthy attended: Online certification course for Current Regulatory Requirements for conducting Clinical Trials in India for Investigational New Drugs 2.0. conducted by National Programme on Technology Enhanced Learning (NPTEL); appeared for online examination on 17th December 2020.
- 4. Dr. Bhaskar Krishnamurthy attended :Online certification course for Regulatory Requirements for Medical Devices including In Vitro Diagnostics in India. Version 2.0 conducted by National Programme on Technology Enhanced Learning (NPTEL); appeared for online examination on 17th December 2020.
- 5. Dr. Snehalata Gajbhiye has taken 8 lectures on topics related to research ethcs in 8 different workshops.
- 6. Dr. Sai Kulkarni has attended Foundation Course in Good clinical Practice and Current Challenges for Integrative Health Care, 'Digital Ethics committee, is that the way forward in India?' and FMES 8th National Bio ethics conference.
- 7. Dr. Yashashri Shetty: Conducted half day workshop for training in research ethics in terms of "Ethics committee role and responsibilities toethics committee members of Inter System Biomedical Ethics Committee, Sthanakwasi Jain Aradhana Dham, 17, Khandubai Desai Road, Ville Parle(W), on Jan 9th 2020
- 8. Dr. Yashashri Shetty: Training programs attended by IEC members and IEC staff: 1 IEC NDCTR and Site Monitoring on 31st October 2020 online via Google App organised by Seth GSMC and
- 9. Dr.Yashashri Shetty: Conducted half day workshop and covered "Ethical consideration in research "and "NDCTR 2019" to Ethics committee members of Aditya Jyot Eye Hospital, Wadala, Mumbai
- 10. Dr. Yashashri Shetty: Review and Approval of protocol by Ethics Committee, session taken in Pharmasteer Orientation Programme for post graduate students (400 PGs attended throughout India) a joint venture between Department of Pharmacology & Therapeutics and Astrazeneca .
- 11. Dr. Yashashri Shetty: Sessions taken in RMW for postgraduate students (Surgery, orthopaedics, dermatology ,pharmacology and psychiatry) at KEMH on 15th and 16th Dec 2020. Topics covered were "Selection of endpoints", "ICMR guidelines 2017", "Role of investigator", "Issues with Informed consent process"
- 12. Dr. Yashashri Shetty: Conducted GCP training for OT/PT and Pharmacology students on 21st Dec 2020 at KEMH. Topic covered were "Role of sponsor"

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for Clinical Trial, Bioavailability and Bioequivalence Study and Relating to Biomedical and Health Research (BHR).

Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India. Established - 6<sup>th</sup> January 1987

Registered by:

Central Licensing Authority with Re-Registration No.ECR/229/Inst./MH/2013/RR-19 issued Under New Drug and Clinical Trials Rules, 2019. Valid from April 22, 2019 thru April 21, 2024 and Government of India, Ministry of Health & Family Welfare,

Department of Health Research, File No. - EC/NEW/INST/2019/202, Provisional certificate dated 12-OCT-2019.

Recognized by:

Western Pacific Region (FERCAP) for its compliance with international and local standards in ethical review.

Valid from Nov 20, 2016 thru Nov 19, 2020.

Accredited by: NABH: National Accreditation Board for Hospitals & Healthcare Providers (Constituent Board of Quality Council of India).

Valid from May 19, 2018 thru May 18, 2021 Certificate No. EC-CT- 2018-0027

### 2. Presented papers related to research ethics at conference:

- a) Dr.Yashashri Shetty: Faculty at 13th annual conference in Mumbai on 24-25 January 2020 of Indian Society for Clinical Research (ISCR) at Hotel Taj Lands End.Session Taken was on "Regulatory Inspections and Audits: Lessons Learnt- Site, EC and PV".
- b) Dr. Snehalata Gajbhiye: Poster presentation titled "A review of clinical studies in the area of COVID-19 registered in the Clinical Trials Registry of India was presented in 7th National Conference of Forum for Ethics Review Committees in India, FERCICON 2020 during 27-29th November, 2020 by Department of Pharmacology, PGIMER.
- c) Dr. Snehalata Gajbhiye: Poster presentation by Gajbhiye SV, Kamat SK, <u>Prajapati M</u> of the paper titled "A review of clinical studies in the area of COVID-19 registered in the Clinical Trials Registry of India' in 7th National Conference of Forum for Ethics Review Committees in India, FERCICON 2020 during 27-29th November, 2020 organized by Department of Pharmacology, PGIMER.
- d) Bavdekar SB: Ethics Committees: Action during pandemic and lockdown situations. \*J Postgrad Med. 2020; 66(3):119-22
- e) Dr.Yashashri Shetty :Presented paper on 8th December 2020 on "Multi-country Survey (17 Countries) on Covid Public Health Measures India Data" at" 20th FERCAP ONLINE INTERNATIONAL ANNUAL CONFERENCE ,December 7-9, 2020 Hosted by the National Institutes of Health
- f) Dr. Yashashri Shetty: University of the Philippines Manila.

### 3. Publication related to research ethics in scientific journals:

a) Dr. Snehalata Gajbhiye: Gajbhiye SV, Jalgaonkar SV, Dabba SG, Surve SV, Lad MS. Assessing completion reports for compliance with institutional ethics committee approved protocols: An observational study. Indian J Med Ethics. Published online on March 2, 2020

### 4. Winning Prizes for papers /posters related to research ethics at conferences:

- a) Dr. Snehalata Gajbhiye: Second prize awarded to Gajbhiye SV, Kamat SK, Prajapati M for paper titled "A review of clinical studies in the area of COVID-19 registered in the Clinical Trials Registry of India' presented in 7th National Conference of Forum for Ethics Review Committees in India, FERCICON 2020 during 27-29th November, 2020 by Department of Pharmacology, PGIMER.
- b) Best presenter award Yashashri Shetty , Medha Rajappa, Sudha Ramalingam, Vinita Agarwal, Gaurav Narula. "Perceptions about Ethics of Public Health Behavioral Interventions during the Covid 19 Outbreak" at" 20th FERCAP Online International Annual Conference December 7-9,2020, organised by National Institutes of Health University of the Philippines Manila.

Dr. Yashahsri Shetty Member Secretary IEC-I Ms. Shilpshree Palsule Member Secretary IEC-II

for Sujakuents

Dr. Amey Rojekar Member Secretary IEC-III

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