

Addendum 1 dated 21st May 2021 effective from 15th July 2021 to following SOPs version 6.1

1. Addendum 1 dated 21st May 2021 to SOP 02: Constituting Institutional Ethics Committee
2. Addendum 1 dated 21st May 2021 to SOP 05: Management of Initial protocol submissions.
3. Addendum 1 dated 21st May 2021 to SOP11-B: Review of SAE reports and UAE
4. Addendum 1 dated 21st May 2021 to SOP12: Site monitoring visit.
5. Addendum 1 dated 21st May 2021 to SOP 17: Responding to research participants request or complaint.

1. Addendum 1 dated 21st May 2021 to SOP 02: Constituting Institutional Ethics Committee

1) In continuation with SOP 02/V6.1, effective date 1st August 2020 point no. 5.6 on page no. 12 of 239
Section 'Resignation and disqualification of members'

- A member desirous of resigning from the Ethics Committee is required to give at least two months' notice before the resignation becomes effective.
- The resignation letter will be addressed to the Dean of the institution and shall be submitted to the IEC office. The notice period shall begin from the date it is received in the IEC office.
- After the receipt of the letter, the IEC secretariat will issue an acknowledgment of receipt to the concerned member and shall put up the resignation letter to the Member- Secretary and/ or Chairperson.
- The Member- Secretary under the orders of the Chairperson shall forward the letter to the Dean within a period of 10 days from the receipt of the resignation letter with appropriate remarks/ recommendations: may be accepted/ may not be accepted citing reasons/ decision may be deferred citing reasons/ any other appropriate remark or recommendation citing reasons.
- The Chairperson in consultation with the Member- Secretary, is at liberty to waive the mandatory notice period and state so in the recommendation to the Dean
- The Chairperson, in consultation with the Member- Secretary shall take appropriate steps to appoint another member in place of the resigning member so that the composition of the IEC continues to be in compliance with the applicable regulations and SOPs
- If a Member- Secretary desires to resign from the post of Member- Secretary, the notice period shall be for a minimum period of 3 months. The rest of the procedure will be the same
- A Member- Secretary can opt for resigning from the post of Member- Secretary while continuing in the post of Member of the IEC
- If the Chairperson decides to recommend to the Dean the acceptance of resignation of the Member- Secretary, he/ she may simultaneously recommend to the Dean that any affiliated member of the IEC may be appointed as the Member- Secretary
- The Member- Secretary who has submitted the letter of resignation, shall continue to work as and dispose of the responsibilities of the Member- Secretary till the time the resignation is accepted by the Dean and the Member- Secretary is relieved of the responsibilities by the Chairperson of the


DEAN 29/07/2021.
Seth G. S. Medical College,
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Institutional Ethics Committee-1. If the Member secretary is willing to continue as member of the board, such decision will be taken by the Head of the institution.

- Once the resignation given to IEC by MS the same person should not be preferably appointed as MS in future.

In consultation with the Member- Secretary, Board shall decide whether the resignation letter needs to be submitted by a member or Member Secretary (MS) to the Chairperson and Chairperson needs to inform to the Head of the Institute and initiate procedure for the next appointment or vacancy. In the interim period, Chairperson / board will appoint the acting Member Secretary and he /she will take charge till the appointment of next Member Secretary.

MS should give notice two months prior to resignation to the appointing officer, (The Dean). In the meantime, till the new successor takes over, the prior MS will continue on the post or the Acting Member Secretary will take over temporarily as MS.

2) Member list as on 21st May 2021:

Sr. No.	Name	Qualification with Specialization	Current Organization	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee	Gender
1.	Dr. Padmavathy Menon	M.D., Medicine DM, Endocrinology	Jupiter Hospital, Thane	Chairperson	Non-affiliated	F
2.	Dr. Yashashri Shetty	M.D., DBM. Associate Professor (Pharmacology & Therapeutics)	Seth GS Medical College and KEM Hospital	Member Secretary (Basic Medical Scientist)	Affiliated	F
3.	Dr. Urmila Thatte	M.D., DNB., Ph.D. Emeritus Professor (Clinical Pharmacology)	Seth GS Medical College and KEM Hospital	Member (Basic Medical Scientist)	Affiliated	F
4.	Dr. Bhaskar Krishnamurthy	D.M.(Pharmacology) M.D.(Pharmacology, M.B.B.S Assistant Professor (Clinical Pharmacology)	Seth GS Medical College and KEM Hospital, Mumbai.	Member (Basic medical scientist)	Affiliated	M
5.	Dr. Sandeep Bavdekar	MD (Pediatrics), Diploma in Child Health, Certificate in Hospital & Health Care	Consultant	Member (Clinician)	Non-affiliated	M

		Management Diploma in Information Technology (DIT)				
6.	Ms. Meera Shah	M.S.W (Social Work) M. A. (Clinical Psychology) Diploma In Journalism, N.L.P., R.E.T. and Counseling	Consulting Psychologist.	Social Scientist	Non-affiliated	F
7.	Ms. Veena Johari	L.L.B., LL.M.	Independent Lawyer	Member Legal Expert	Non-affiliated	F
8.	Dr. Sai Kulkarni	M.A, PhD in Economics	-	Member (Lay person)	Non-affiliated	F
9.	Dr. Sanjeevani Zadkar	MBBS, MD Associated professor (Anaesthesia)	Seth GS Medical College and KEM Hospital, Mumbai	Member (Clinician)	Affiliated	F
10.	Dr. Kaizad Damania.	M. D., DNB., F.C.P.S., D.G.O., D.F.P. Professor (Obstetrics & Gynecology)	N.Wadia Maternity Hospital Mumbai.	Member (Clinician)	Non-affiliated	M
11.	Dr. Charulata Londhe	M. D. (Internal Medicine) Associated Professor (Medicine)	Lokmanya Tilak Municipal Medical College and General Hospital, Sion, Mumbai.	Member (Clinician)	Non-affiliated	F
12.	Dr. Milind Tullu	MBBS, MD (Pediatrics), DNB (Pediatrics), DCH (Diploma in Child Health), 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, Mumbai	Member (Clinician)	Affiliated	M
13.	Dr. Monty Khajanchi	DNB (Surgery), MBBS Assistant Professor (General Surgery),	Seth GS Medical College and KEM Hospital, Mumbai	Member (Clinician)	Affiliated	M
14.	Dr. Dheeraj Kumar	DM (Cardiology), DNB (Cardiology) Assistant Professor (Cardiology)	Seth GS Medical College and KEM Hospital, Mumbai	Member (Clinician)	Affiliated	M

3. Addendum 1 dated 21st May 2021 to SOP 05: Management of Initial protocol submissions.

- a) In continuation with SOP 05/V6.1 effective date 1st August 2020 on page no. 65 of 239 Note:
A hard copy set (sponsored study in Box File & non sponsored study in card board file) a typed version (no handwritten text will be accepted) on A 4 size paper arranged in a file in orderly manner.
- b) In continuation with SOP 05/V6.1 effective date 1st August 2020 point no. g on page no. 66 of 239 for online payment details for protocol review processing fees following are the Principal Investigators responsibilities:

Protocol review processing fees for all types of studies:

	Project Types	Initial review processing fees		Periodic review processing fees		Annual review processing fees	
		Fees + TDS	Total amount	Fees + TDS	Six monthly	Annual Fees + TDS	Annual Fees
1	Pharmaceuticals sponsored project	Rs. 85,000/ +TDS (10%)	Total Rs. 94,445/-	10,000/- +TDS (10%)	Total Rs. 11,111/-	Rs. 20,000/- + (TDS 10%)	Total 22,222/-
2	Government sponsored projects	Rs. 10,000/- + TDS (10%)	Total Rs. 11,111/-	2,500/- + (10% TDS)	Total Rs. 2,750/-	Rs. 5,000/- + (TDS 10%)	Total Rs. 5,500/-
3	Thesis / Dissertation	Rs. 1,500/-		NA	NA	NA	NA
4	All academic non- sponsored projects (Including DNB, DM, Nursing, PhD Research)	Rs. 2,500/-		NA	NA	NA	NA
5	Funded studies	Budget ranging from 5 to 25,00,000/- IEC charge- Rs. 10,000/- per project Above 25 lakhs for every 5,00,000/- in addition – charges are Rs.1,000/- + TDS 10%)		NA	NA	NA	NA

- No cash payment will be entertained.
- The processing fees shall be collected at the time of submission of the project.

- The **sponsored projects** fees will be accepted by cheque / demand draft/NEFT which will include the TDS, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College& KEM Hospital'.
- The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
- The **protocol** review processing fees will be taken by online **only through following details:**

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	32127685176
Account Type:	Saving
Name of Bank:	State Bank of India
Add of Bank:	PO Bag No. 6034, Mitra Dham Bldg, Elphinston Road, JB Road, Parel T.T., Mumbai 400 012.
IFSC Code:	SBIN0001884
MICR Code:	400002064
PAN No:	AABTS5336G

The protocol review processing fees for **all type of studies** will always be accepted through cheque / online.

- Initial submission process will be completed with subject to above payment fulfillment and submission of all mandatory documents.

c) In continuation with SOP 05/V6.1 effective date 1st August 2020 Page 65 of 239, section g) The processing fees details, 5th category:

Funded study:

Funder and Sponsor is defined

Funder - who provides bulk of the funding for the trial. Money is usually like a grant for the advancement of science or for public good.

Sponsor - who provides financial support for the trial in return for something or for varied reasons, that could range from trying out a new product, to promoting their product, or their company or organization, or providing an opportunity to try out their product - in return for access to (anonymized) data collected from the trial, or promoting their product, or comparing their product to other products or processes (that include comparing with competitor products, etc.), or conducting a trial for future commercial gain, or obtaining samples, using them, storing them for future use or as corporate responsibility, etc.

Thus, in a PI-initiated trial that is funded by industry (use of words "industry", "company", "pharma company" interchangeably here), it is important to ensure that:

1. the funding is not to obtain and/or use the data for commercial gain for the company
2. the funding is not to promote the product of the company
3. the company would receive only a summary report of the trial
4. the report of the trial cannot be used by the pharma company for commercial gain; or to obtain licenses or permissions, etc.
5. the company will not have access to participant (anonymized) data, CRF, reports, or will not be sent samples for testing, storage, etc.
6. the company will not provide compensation or insurance for the trial participants or the trial. Except for injury that may result due to manufacturing defects or problems, the PI will be responsible for compensation for any injury.
7. the company has no control on the publication of the trial by the PIs, and the PIs are not obliged to inform or share their drafts or publications with the company

8. if the PI discovers or invents something new with the product of the company, the intellectual property rights would be with the PI and/or the institute and not the company
9. Company may at most do a financial audit of the funding provided to the PI. But, company cannot do an audit of or monitor the trial.
10. Registering the trial on the CTRI website would be the responsibility of the PI or the institution, but not the funder company.

CTA / MOU between Funder and Department conducting the study in particular should address the following clauses:

- a. The title must mention through whom the Institutes are a party i.e. the Head of the Institutes, and their names, and the Departments in the institutes that are involved, and the name of the PI or Co-PI, designation, etc. Please mention addresses of all the parties too.
- b. The MoU/CTA must state the purpose of the project/ trial, and if there are any financial transactions or payments to be made by one party to the other for the purpose of the project/ trial.
- c. The roles and responsibilities of each party to the MoU should be stated. It also needs to be stated who will be responsible for taking the informed consent, conduct of the trial, final report writing, etc.
- d. Material Transfer Agreement or clauses need to be added to the MoU/CTA or a separate agreement to be made for MTA, where samples collected by one party will be transported to another party (who will be responsible for the transport, how will it be done, who will ensure that the samples will not be adulterated or tampered with, at what temperature will they be transferred, etc).
- e. It also needs to be stated that the samples sent will be anonymized by KEM, to maintain the confidentiality of the participants.
- f. It needs to be stated that the tests conducted by one party on the samples shared, whether the results will be shared with KEM or not? Will those results be informed to the participants after the trial is completed? How the results will be shared also needs to be stated in the MoU/CTA.
- g. Insurance - it needs to be stated in the MoU/CTA which party will take the insurance and/or pay compensation to the participants in case of any injury or adverse or serious adverse event. Which party will pay for the Compensation for travel, time, wages, etc. for participating in the research also needs to be stated in the MoU.
- h. The study should be registered on the CTRI website, and which party will be responsible for the same should also be mentioned. If DCGI Permission is required for the study, it needs to be stated, and which party will be responsible for the same should be stated in the MoU/CTA.
- i. The parties that can publish and report the study/ trial/ project, should be stated clearly in the MoU/CTA. If permission of another party is required, then that also should be stated.
- j. The MoU/CTA should mention the clauses on confidentiality, not only of the product or project, but also of the data generated, and the personal information of the participants of the trial/ research/ project.
- k. The MoU /CTA must state that qualifications of the persons involved in the trial/ project, and that they would follow the law, rules, guidelines, etc. in relation to conducting research trials.
- l. There should be a clause on arbitration or amicable settlement of any disputes that may arise between the parties. The parties must try to amicably settle the dispute, however, if it remains unresolved, then a common arbitrator could be involved to resolve the dispute. If the dispute does not still get resolved, then each party to appoint an arbitrator, and agree upon a common arbitrator to resolve the disputes under the Arbitration Act, 1996. The jurisdiction of the arbitration should be Mumbai.

4. Addendum 1 dated 21st May 2021 to SOP11-B: Review of SAE reports and UAE

SOP11-B Page 153 of 239 Section 5.1 follow CDSCO NOTICE dated 25-02-2021 regarding SAE reporting on SUGAM portal.

5. Addendum 1 dated 21st May 2021 to SOP 12/6.1 Site monitoring visit:

- a. Page 165 of 239, Section 5.3 During the monitoring visit; To review the log book in the room where IP (investigational product) is stored .
- b. Page 170 of 239, Annexure 1, point 21, added sub point
Is the log book available in the IP (investigational product) room Yes No N/A
Comments (if any) _____

4. Addendum 1 dated 21st May 2021 to SOP 17: Responding to research participants request or complaint.

SOP 17 Page 201 of 239: Annexure 1 (Vernacular version i.e. Hindi and Marathi added.)

अनुलग्नक १

एएक्स ०१/एसओपी १७/वी ६.१

प्रतिभागी का अनुरोध / शिकायत अर्जी

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संपर्क करें:	
पता:	
फ़ोन:	
प्रतिभाग लेने वाले अध्ययन का शीर्षक:	
प्रतिभागी होनेवाली प्रारंभिक तारीख:	

मांगी गई जानकारी / शिकायत / पूछताछ	
कार्रवाई का वर्णन:	
अन्तिम निर्णय :	

नितीमता समिती सदस्य सचिव के हस्ताक्षर:

तारीख:

परिशिष्ट १

एएक्स ०१ / एसओपी १७ / व्ही ६.१

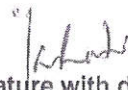
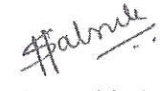
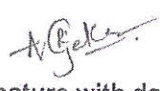
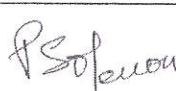

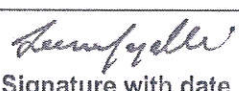
सहभागीची विनंती / तक्रार नोंदवण्याचा फॉर्म

तारीख	
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संपर्क:	
पता:	
फोन:	

सहभागी अभ्यासाचे शीर्षक:	
सहभाग घेतल्याची तारीख :	
विनंती केलेली माहिती / तक्रार / प्रश्न	
कारवाईचे वर्णन: अंतिम निर्णय:	

नैतिक संस्थेच्या सदस्य सचिवाची सही

तारीख

Prepared by	Dr. Yashashri Shetty, Member Secretary, IEC-I	 Signature with date
Reviewed by	Ms. Shilpshree Palsule, Member Secretary, IEC-II	 Signature with date
	Dr. Amey Rojekar, Member Secretary, IEC-III	 Signature with date
Approved by	Dr. P. S. Menon, Chairperson, IEC-I	 Signature with date
	Dr. Subodh Sirur, Chairperson, IEC-II	 Signature with date
	Dr. Leena Gangolli, Chairperson, IEC-III	 Signature with date


29/07/2021

DEAN

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Mumbai - 400 012, India,