

Addendum 2 dated 27th December 2022
effective from 2nd January 2023 to SOPs version 6.1 and SOP 22 & 23

1) Software e-EC discontinuation and submission of a new study proposal via hard copy & soft copy via pen drive.

As the e-EC software requires high maintenance fees the IEC has decided to discontinue the software and to take hard copy study proposal along with checklist (detail instructions available on www.kem.edu) and scanned soft copy (PDF version) on pen drive

2) The review of projects by IEC members, will be performed online (individual basis) and in the scheduled IEC meeting. The queries raised by the members on the protocol and related documents will be communicated to IEC secretariat either via email or via project assessment annexure.

3) Hybrid full board meeting as per requirements:

In situations where one or two members are unable to come physically then the review of the studies may be done through virtual / hybrid EC meeting ensuring appropriate scientific and ethical review and fulfilling the quorum requirements. EC members present during the virtual / hybrid meeting should decide through consensus or cast online vote expressing their decision. Any disagreement to be recorded with reasons.

Meeting could be digitally recorded (audio/video) with permission of members and secretariat is responsible to note the attendance/ participation in the online meeting.

4) All Investigators should note the following revised information pertaining to the IECs protocol review processing fees:

- a. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
- b. Payment should be done to DJST's Bank of Maharashtra only. DJST has strictly prohibited IEC transactions to their SBI account.
- c. The protocol review processing fees for all type of studies will always be accepted through cheque / online.
- d. If any transaction made by mistake to SBI, IEC will not be responsible for consequences.
- e. No cash payment will be entertained. Don't pay cash via bank also.
- f. For non-sponsored projects, detailed screen shot for payment details need to submitted to IEC and if required to DJST for cross verification (transaction ID/Reference no. etc..)
- g. Transaction details (screen shot)
- h. The protocol review processing fees of all types of projects will be taken by online only through following details:

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	60236880148
Account Type:	Saving
Name of Bank:	Bank of Maharashtra, Branch Parel
Add of Bank:	Vikas Apartment, Dr. Ambedkar Road, Parel, Mumbai, 400012.
IFSC Code:	MAHB0000079
MICR Code:	400014011
PAN No:	AABTS5336G

- i. For sponsored projects fees, please note the following requirements:
 - ✓ 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'.
 - ✓ Please note a letter from sponsor is required (on sponsors letterhead) mentioning the following details: Gross amount, TDS amount deducted and the net amount to be paid as IEC review processing fees.

1.	Payer / remitter's reference no.	
2.	Payer PAN number	
3.	Beneficiary details	
4.	Payment date	
5.	Trans currency	
6.	Payment method	
7.	Transaction reference number	
8.	Net amount	
9.	TDS	
10.	Gross amount	

✓ Please note if sponsor / investigator is not deducting any TDS then they have to provide a letter stating that no TDS has been deducted and actual fees of i.e. Rs. 85,000/- is being paid.

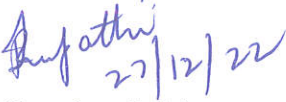







j. TDS certificate should be provided quarterly.

k. Protocol review processing fees:

	Project Types	Initial review processing fees in INR		Periodic review processing fees in INR Six monthly Review		Annual review processing fees in INR	
		Gross amount Less 10% TDS	Net Amount	Gross amount Less 10% TDS	Net Amount	Gross amount Less 10% TDS	Net Amount
1	Pharmaceuticals sponsored project	94,445/- Less 9,444.50/-	85,000.50/-	11,112/- Less 1,111.20/-	10,000.80/-	22,223/- Less 2,222.30/-	20,000.70/-
2	Government sponsored projects	11,112/- Less 1,111.20/-	10,000.80/-	2778/- Less 277.80/-	2,500.20/-	5,556/- Less 555.60/-	5,000.40/-
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 5,00,000/- 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

5) Initial submission process will be completed subject fulfillment of above payment and submission of all mandatory documents.

6) No continuation review reports will be entertained without processing fees. Study coordinators should follow deadlines strictly.

Prepared by	 Signature & date Dr. Raakhi Tripathi Member Secretary IEC-I		
Reviewed by	 Signature & date Dr. Nithya Gogtay Jt. Member Secretary IEC-I	 Signature & date Dr. Priyanka Prasad Member Secretary IEC-II	 Signature & date Dr. Swapna Kanade Member Secretary IEC-III
Approved by	 Signature & date Dr. Manju Sengar Chairperson, IEC-I	 Signature & date Dr. Sunil Kuyare Chairperson, IEC-II	 Signature & date Dr. Mohan Karmarkar Chairperson, IEC-III
Accepted by	IEC-I	IEC-II	IEC-III
 Dr. Sangeeta Ravat, Dean, Seth GSMC and KEMH Signature and date Dean, K.E.M.H. & Seth G.S.M.C., Parel, Mumbai - 400 012			