SOP05-A/V7.1 Management of Initial Protocol Submissions, Effective from 9th May 2026

1. **The processing Fees Details:**
   Institutional Ethics Committee (IEC) shall charge an application fee for review of research projects. The Institute shall not charge an EC application fee.

   15.1) **Fee Structure:**
   - The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
   - Payment should be done to DJST's Bank of Maharashtra only. DJST has strictly prohibited IEC transactions to their SBI account.
   - The protocol review processing fees for all type of studies will always be accepted through cheque / online.
   - If any transaction made by mistake to SBI, IEC will not be responsible for consequences.
   - No cash payment will be entertained. Don't pay cash via bank also.
   - 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.)
   - Transaction details (screen shot)
   - 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

   - 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	
11.	Payment receipt in the name of	

     - ✓ 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.

   - TDS certificate should be provided quarterly.
   - 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

- Initial submission process will be completed subject to payment of initial review fees and submission of all mandatory documents.
- Processing fees for periodic review report need to be submitted at the time of submission of periodic review report.
- If a sponsored / funded study is withdrawn after the initial review, the IEC processing fees for initial review has to be paid in full. Without this the project will not be closed for IEC records and IEC will not issue the closure letter for the study for the sponsor.

16. The research study may be self funded / intra or extra mural funded. The PI should distinguished between funding agency and sponsor. Sponsor is defined as a person, a funding agency or an institution or an organisation responsible for initiation and management of a clinical trial / clinical study.

    Funding agency is defined as a person, a funding agency or an institution or an organisation who provides bulk of the funding for the trial. Money is usually like a grant for the advancement of science or for public good.

    Thus, in a PI-initiated trial that is funded it is important to ensure that:

- the funding is not to obtain and / or use the data for commercial gain for the funding agency
- the funding is not to promote the product of the funding agency
- the funding agency would receive only a summary report of the trial
- the report of the trial cannot be used by the pharmaceutical industry if it is a funding agency for commercial gain; or to obtain licenses or permissions, etc.
- the funding agency will not have access to participant (anonymized) data, CRF, reports, or will not be sent samples for testing, storage, etc.
- the funding agency will not provide compensation or insurance for the trial participants or the trial. The PI will be responsible for free medical management and providing financial compensation for any trial related injury.
- the funding agency 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 funding agency

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

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

- 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.
- 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.
- 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.
- 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.).
- It also needs to be stated that the samples sent will be anonymized by KEMH, to maintain the confidentiality of the participants.
- It needs to be stated that the tests conducted by one party on the samples shared, whether the results will be shared with KEMH. The results will be shared also needs to stated in the MoU/CTA and process of result sharing need to be specified.
- It needs to be stated in the MoU/CTA which party will take the trial insurance policy and/or pay compensation to the participants in case of any injury or adverse or serious adverse event.
- 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.
- 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.
- 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.
- 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.
- 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.