



Title: IEC Review Fee Structure

SOP Code: AX32-VI /SOP01 /V6

Effective from 01 Nov 2022

Valid up to 30 Oct 2025

1. Title:

IEC Review Fee Structure

1.1 SOP Code:

AX32-V1 /SOP01 /V6

1.2 Application Date

01 Oct 2022

1.3 Validity period

3 (Three) years

1.4 Authors:

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1. Purpose

1.1 This Standard Operating Procedure (SOP) describes the administrative procedure of obtaining IEC Fee.

2. Scope

2.1 This SOP applies to IEC reviewing fee structure for new and old study proposal at various stages.

2.2 This SOP applies to charge a reasonable monetary fee to cover the expenses related to optimal functioning of IEC and IEC secretariat including document archiving.

3. Responsibility

3.1 Head of the Institution, as per the hospital policy, guides the administrative officer of IEC secretariat in formulating the IEC fee structure.

3.2 IEC secretariat is responsible for levying and revenue collection records

3.3 IEC Member Secretary in consultation with IEC Chairperson is responsible for supervising and monitoring of policy implementation.

4. Flow Chart

S. No.	Activity	Responsibility
1	Describing Fee structure for IEC activities	Head of the Institution, IEC Secretariat
2	Maintaining records	IEC secretariat
3	Supervision and Monitoring	IEC Secretary and IEC Chairperson

5. Detailed Instruction:

5.1 IEC fee for reviewing new study proposal (Option A):

5.1.1 Researchers shall submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per AX13-V1 /IEC SOP01 /V6

5.1.2 Researcher shall ensure to pay a sum of INR 1,25000/- exclusive of all levied taxes, for initial reviewing of new study proposal before the actual date of IEC meeting.

5.1.3 Researcher may submit new study proposal for IEC reviewing prior to national / global regulatory approval in meeting the project completing timelines.

5.1.4 Researcher may hope to get and 'conditional IEC approval in absence to national regulatory approval'

5.1.3 Researcher shall ensure to submit /notify national / global regulatory approval before conducting the new drug study protocol at this site.

5.1.4 In case researcher fail to obtained national / global regulatory approval with the stipulated period of 9 months, IEC shall charge a renewal of approval fee of INR 50000/- before the actual date of IEC meeting.

5.2 IEC fee for reviewing of study document amendment of approved study:

5.2.1 Researcher shall ensure to submitted amended document for IEC reviewing mentioning the "changes" made and "reasons" for changes in approved protocol.



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5.2.2 IEC secretariat staff in consultation with IEC member Secretary shall label these changes as 'minor administrative changes' or major safety changes' by assessing the risk.

5.2.3 Researcher shall ensure to pay a sum of INR 50000/-per study amendment document for IEC reviewing before the actual date of IEC meeting.

5.3 IEC fee for SAE (Serious adverse event) analysis:

5.3.1 IEC secretariat staff ensure to collect following principal investigator submitted SAE documents within regulatory timelines:

5.3.1.1 IEC notification of initial SAE report.

5.3.1.2 Sponsor notification of initial SAE report.

5.3.1.3 Regulatory notification of initial SAE report. (Table -5)

5.3.1.4 SAE Investigation reports (lab/radiology etc.)

5.3.1.5 SAE medical management document

5.3.1.6 IEC notification of 'investigator analysis report'

5.3.1.7 Subject / participant source file /document for IEC reviewing

5.3.1.8 Power point presentation of SAE for IEC

5.3.1.9 Researcher shall ensure to pay a sum of INR 15000/-per SAE document for IEC review and analysis before the actual date of IEC meeting.

5.4 IEC fee for IEC notification after study closeout

5.4.1 IEC secretariat staff ensure to label post study closeout document e.g. CIOM / SUSAR / CSR

5.4.2 Researcher shall ensure to pay a sum of INR 10000/-per IEC document notification after study close out.

5.5 IEC fee for archival

5.5.1 IEC secretariat staff shall ensure that study documents to be maintained by IEC for records as per annexure AX27-V1 /SOP01 /V6

5.5.2 IEC Secretariat staff ensure to archive these document for 15 years with project name, date of archival and till date for 15 years.

5.5.3 Researcher shall ensure to pay a sum of INR 75000/-per study archival documents for 15 years.

5.6 IEC fee for reviewing new study proposal (Option B):

5.6.1 Researchers shall submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per AX13-V1 /IEC SOP01 /V6

5.6.2 Researcher shall ensure to pay one time IEC fee of sum of INR 2,50000/- exclusive of all levied taxes, for initial reviewing of new study proposal and any amendment review in future, before the actual date of IEC meeting.



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5.7 IEC fee for 'Expedited reviewing' new study proposal with 15 working days (Option C):

5.7.1 Researchers shall submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per AX13-V1 /IEC SOP01 /V6

5.7.2 Researcher shall ensure to pay one time IEC fee of sum of INR 3,00,000/- exclusive of all levied taxes, for initial reviewing of new study proposal and any amendment review in future, before the actual date of IEC meeting.

5.8 IEC payee detail:

Payee name for IEC Fee /amendment /Archiving / one time / expedited review	Bhagwan Mahaveer Cancer Hospital and Research Centre
Name of the Bank	ICICI Bank Ltd.
Branch Name	Sitapura Pratap Nagar
Name of City and pin number	Jaipur-302017
Account Number	674805000020
IFSC Code	ICIC0006748
PAN Number	AAATB2618K
GSTN number	08AAATB2618KZT

5.9 Frequency of IEC meeting and submission of study documents:

Frequency of IEC meeting	Regular meeting every 3 months in an year
Number of sets of study documents	10+1 Total sets of hard and soft copies
Timeline for study document submission	15 days before the actual date of conducting IEC
Language of ICF study documents	Hindi and English

5.10 Turnaround time for IEC decision and result communication:

5.10.1 IEC Member secretary and IEC Secretariat staff shall prepare the minutes of the meeting and communicate results to study stakeholders in 3 weeks' times for regular IEC meeting and in 2 weeks' times in case of 'expedited IEC study review'.

6. Glossary

Beneficence	To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.
Risk	Probability of harm or discomfort to research participants. Acceptable risk differs depending on the conditions inherent in the conduct of research