Institutional Review Board
Malabar Cancer Centre (IRB, MCC)

Title: Preparing Standard Operating Procedures (SOPs) Writing, Reviewing, Distributing & Amending SOPs

Edited By : SOPs Development Team, Malabar Cancer Centre

Approved By

Chairperson Member Secretary
(Institutional Ethics Committee)

SOP 01/VER1 **Pages: 1 to 13**

1.1 PURPOSE

This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the Institutional Review Board (IRB), Malabar Cancer Centre (MCC).

The SOPs will provide clear, unambiguous instructions to conduct activities of the IRB in accordance with the ICMR guidelines 2006, Schedule 'Y" (Drugs and Cosmetic Act 1940: Amendment 20th Jan 2005), WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) - Good Clinical Practice (GCP)

1.2 SCOPES

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the Institutional Review Board (IRB) of Malabar Cancer Centre (MCC).

1.3 RESPONSIBILITIES

It is the responsibility of Member Secretary of the Institutional Ethics Committee (IEC) of MCC along with the consent of the Director, MCC, to appoint the SOP Team to formulate the SOPs. SOP team will prepare the draft of the SOPs. The draft SOPs will be reviewed and approved by the IRB members. SOP team will be responsible to amend the SOPs as and when required.

SOPs will be reviewed by the members of IRB , i.e. members of Committees constituting IRB in MCC. The Chairperson of IEC, MCC will give final approval of the SOPs.
The SOPs will then be signed by the Director, MCC, as final approval to implement.

- SOP team will consist of Member Secretary of IEC and one or two Scientific Review Committee members and/or Academic Staffs of MCC. No other person, without the written consent from authorized member of IRB, is entitled to make any changes in SOPs. The IRB Secretariat/ Members or the concerned SOP team will not be responsible for any natural/ill-intentional torturing in SOPs. The SOP team will-

  - Assess the request(s) for SOP revision in consultation with the Member-Secretary of IEC and Chairperson, IEC
  - Propose a new, or modification in existing SOPs as needed
  - Draft the SOP after formatting and suitable coding
  - Review the draft SOP
  - Submit the draft for approval to Chairperson (Ethical Committee)

1.4 DETAILED INSTRUCTIONS

1.4.1 Identify the need for new or amendment to the SOP

Any member of the IRB or member of the Office of IRB or Academic Council Member or Investigators/ Researchers, can make a request for revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP. The request can put forth by using the Request Form for Formulation of new SOP/ Revision of an SOP Form (*ANX5-VER1/SOP01/VER1)*. This Formulation of new SOP/ Revision of an SOP Form (*ANX5-VER1/SOP01/VER1)* is submitted to the Chairperson, IEC. The Member-Secretary of IEC will inform all IRB (both SRC & IEC) members about this request in a regular full meeting.

If IRB members agree to the request, the Chairperson/ Member Secretary of IEC will appoint an appropriate SOP team comprising of Member Secretary and suitable members of both committees and/or Academic staffs of MCC. This designated team will proceed with the task of revision / formulation process of the SOP.

If IRB members do not agree to the request, no further action will be taken.

The Member-Secretary of IEC must inform the person/ IRB member who made the request for modification of the SOP in writing about the decision.

1.4.2 Appoint of SOP Team

The Chairperson/Member-Secretary of IEC will constitute an SOP team consisting of the Member-Secretary and two or more members from SRC & IEC who have a clear understanding of the scientific and ethical review process & qualities. The SOP writing team will carry out the subsequent steps (1.4.3 to 1.4.8)

1.4.3 List of relevant SOPs

- All the procedures of the IRB must be written down systematically and step by step
- Organize, devise and name each process
- Make a list of SOPs with coding format (e.g. ***ANX1-VER1/SOP01/VER1)***

1.4.4 Format and Layout designing

Each SOP must be given a number and a title that is self-explanatory and is easily understood.
A unique code number with the format **SOP xx / VER y** will be assigned to each SOP. 'xx' is a two-digit number assigned to a specific SOP. "*VER*" refers to version of the SOP and "y" is a number identifying the version e.g. SOP01/VER1 is SOP number 01 with VER = Version Number 1

Each Annexure (ANX) is unique code with format **ANXn–VERp/SOP xx/VERy**. **e.g.** *ANX1–*
VER1/SOP01/VER1 indicates ANX is Annexure, 1 is Annexure number, VER1 is version 1, belonging to the SOP 01/VER1

Each Appendix will be given unique code with the format **APNn/VERy** e.g. APN1/VER1 indicates APN is Appendix, 1 is Appendix no 1, VER1 is Version no.1.

Each SOP will be prepared according to the template for Standard Operating Procedures (ANX2 – VER1/*SOP01/VER1)*. Each page of the SOP will bear a header with the effective date which is the date of approval of the SOPs by the Chairperson, IEC and the Director, MCC.

The SOP number will be on the left hand corner of the header. The title of the SOP will be on the left hand corner of the footer. The page number will be listed as Page—of—Total pages on the right hand corner of the footer.
The first two pages of each SOP document will be signed and dated by the authors/editors/ SOP team members, the IRB members who have reviewed the SOPs, IRB-IEC Chairperson and Director, MCC.

1.4.5 Preparation and submission of final draft

- All the members of SRC & IEC will review the draft / revised SOP
- During respective IRB meetings, members can put forth their suggestions / comments on the draft / revised SOP
- The suggestions agreed upon unanimously by all IRB members will be incorporated and the final draft SOP will be formulated
- The SOP team would stand automatically dissolved once the IRB takes final decision regarding the SOP.

1.4.6 Final Approval of New/Revised SOP

The final version will be presented to the Chairperson, IEC, MCC for review and approval. The Chairperson will sign. This approved document will then be submitted to the Director, MCC for acceptance. This date or month of approval will be declared as the effective date or month for implementing the SOP.

1.4.7 Implementation, distribution and filing of SOPs

- Approved SOPs will be implemented from the Effective Date or Month

- Approved SOPs will be distributed to IRB members, Head of the Departments, Medical Librarian, Administrative authorities and IRB staff and members according to the distribution list (*ANX4 –VER1/SOP 01/VER1)*.

- When revised version is distributed, the old version will no longer be effective. A copy of the old version will be archived in a master file.
- One complete original set of current SOPs will be archived in the SOP master file, by the IRB Secretariat/Office of IRB and maintained in Malabar Cancer Centre.

- Soft Copy (Scanned & pdf) of the existing SOP Master File will be maintained in the individual offices of Division of Clinical Research & Biostatistics, Division of Cancer Registry, Office of the System Manager, Office of the Director and Medical Records division for sudden back up.

- Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by Member Secretary or authorized individual. A distribution log should be maintained *(ANX6 –VER1/SOP 01/VER1)*

1.4.8 Manage and Archive old SOPs

All the old SOPs should be retained and clearly marked "***SUPERSEDED***" and archived in a file by the Office of IRB. The process of evolution of previous SOPs of the IRB will be documented in a defined format (*ANX3 –VER1/SOP01/VER1*).

*** **A pdf version of the approved SOPs must be put to the Institution's Website & the System Manager & other staffs of Health IT division, MCC, must be aware of and with any amendment done in SOPs.***

References

1. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) Retrieved from *http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version- 2005)*
2. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) Retrieved from - *www.who.int/tdr/publications/publications*
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996) Retrieved form - *http://www.ich.org/LOB/media/MEDIA482.pdf*
4. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) Retrieved from - *http://www.icmr.nic.in/ethical guidelines.pdf*

GLOSSARY

1. ***Effective Date or Month***: The date or month of approval of the SOPs signed and dated by the Chairperson, IEC, MCC and by Director, MCC, and subsequently the SOP is implemented from that date or month.

2. ***Master SOP files***: An official collection of the Standard Operating Procedures (SOPs) of IRB, MCC accessible to all staffs, IRB members, auditors and government inspectors as a paper copy with approval signatures

3. ***Previous SOPs of the IRB***: A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations

4. ***Requestors***: Investigators, Sponsors, Contract Research Organizations, Regulatory authorities, Hospital administrators, and such others

5. ***Revision date*****:** Date/Year by which the SOP may be revised or reviewed.

6. ***Recipients*****:** Stakeholders who would receive a copy of SOP, viz., two categories
    1) IRB Members i.e. SRC Members & IEC Members 2) Non-IRB members i.e. investigators/sponsors/Institutes or Research Organizations undersigned MoU with MCC/ Academic departments of MCC/ Administrative Officers, MCC/ Accounts Officer, Heads of Departments/Divisions of MCC/ Librarian, MCC and other concerns as per MCC administrative decision.

7. ***SRC members***: Individuals serving as regular members of the Scientific Review Committee of IRB, MCC. The Committee has been constituted in accordance with the requirements set forth in ICMR guidelines.
8. ***IEC members***: Individuals serving as regular members of the Institutional Ethics Committee of IRB, MCC. The Committee has been constituted in accordance with the requirements set forth in schedule Y (20th January 2005)

9. ***SOP (Standard Operating Procedure)****:* Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IRB to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.

10. ***SOP Team***: A team of members selected from the IRB, MCC including the Member Secretary, In Charge of Clinical Research & Biostatistics division and any other member of IRB –SRC and/or Academic staff of MCC departments, as identified by the Chairperson/ Member-Secretary of IEC, MCC, who oversee the creation, preparation, review and periodic revision of the IRB, MCC SOPs.

ANX1-VER1/SOP01/VER1

List of SOPs of Institutional Review Board (IRB), Malabar Cancer Centre (MCC)

Sr. No.	SOP Title	SOP Code	No. of Pages
1	Preparing Standard Operating Procedures (SOPs) Writing, Reviewing, Distributing & Amending SOPs	**SOP01/VER1**	**13**
2	Constitution of Institutional Review Board (IRB), MCC	**SOP02/VER1**	**17**
3	Management of Research Study Submission	**SOP03/VER1**	**27**
4	Preparation of Agenda, Procedures for conducting Meetings, Minutes recording	**SOP04/VER1**	**---**
5	Continuous Protocol Review	**SOP05/VER1**	**12**
6	Review of Protocol Deviation/ Violation/ Waiver/ Non-compliance	**SOP06/VER1**	**07**
7	Review of Reports on Serious Adverse Events (SAE)	**SOP07/VER1**	**15**
8	Maintenance of Active project Files, Disposal/Archival of Closed project, Documents Retrieval	**SOP08/VER1**	**07**
9	Documentation of IRB Activities	**SOP09/VER1**	**03**
10	Study Completion Report Review	**SOP10/VER1**	**06**
11	Management of premature Termination/ Discontinuation/ Suspension of the Studies	**SOP11/VER1**	**06**
12	Review of request for waiver of Written Informed Consent	**SOP12/VER1**	**07**
13	Site Monitoring	**SOP13/VER1**	**08**
14	Dealing with patients/ study participants Requests or Complaints	**SOP14/VER1**	**06**
15	Protection of Vulnerable Population in Clinical Research	**SOP15/VER1**	**05**

ANX2-VER1/SOP01/VER1

Template for Standard Operating Procedures (SOP), IRB-MCC

Institutional Review Board (IRB), MCC	
Title: *Title which is self explanatory & easily understandable*	
SOP No.: SOPxx/ VERy	Page:
SOP Code : SOPxx/VERy Effective Date : DD/MM/YYYY Authors : xxxxxxxx Reviewed By : xxxxxxxxx Approved By : xxxxxxxxx	

ANX3-VER1/SOP01/VER1
Document History of the SOP, IRB-MCC

Name of the Author	Version	Effective Date (DD/MM/YYYY)

Details of Superseded SOP, IRB- MCC

Name of the Team/Group	Version	Type (Final/Draft)	Date DD/MM/YYYY	Describe the Main Page

ANX4-VER1/SOP01/VER1

Log of IRB Members receiving SOPs

Serial No.	Name of the Recipient	Designation	SOP Code No..	No. of Copies	Signature	Date
1		Chairperson, IRB-IEC				
2		Member-Secretary, IRB-IEC				
3		Member, IRB-SRC & IRB-IEC				
4		Member, IRB-SRC & IRB-IEC				
5		Member, IRB-SRC & IRB-IEC				

ANX5-VER1/SOP01/VER1

Request for Formulation of New SOPs/Revision of SOPs

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified with the SOP until an authorized replacement is in place

SOP No.:	
Title:	
Details of problems or deficiency in the existing SOP	
Need to formulate an entirely new SOP (i.e. SOP not existing previously)	Date: (DD/MM/YYYY)
Identified By:	
Discussed in IRB(both SRC & IEC) Meeting held on :-	
SOP Revision Required: ☐ YES ☐ NO	
New SOP to be formulated: ☐ YES ☐ NO	
If Yes, to be carried out by Whom?	
If No, why not?	
Date of SOP Revised:	
Date of SOP Approved:	
Date of SOP becomes effective:	

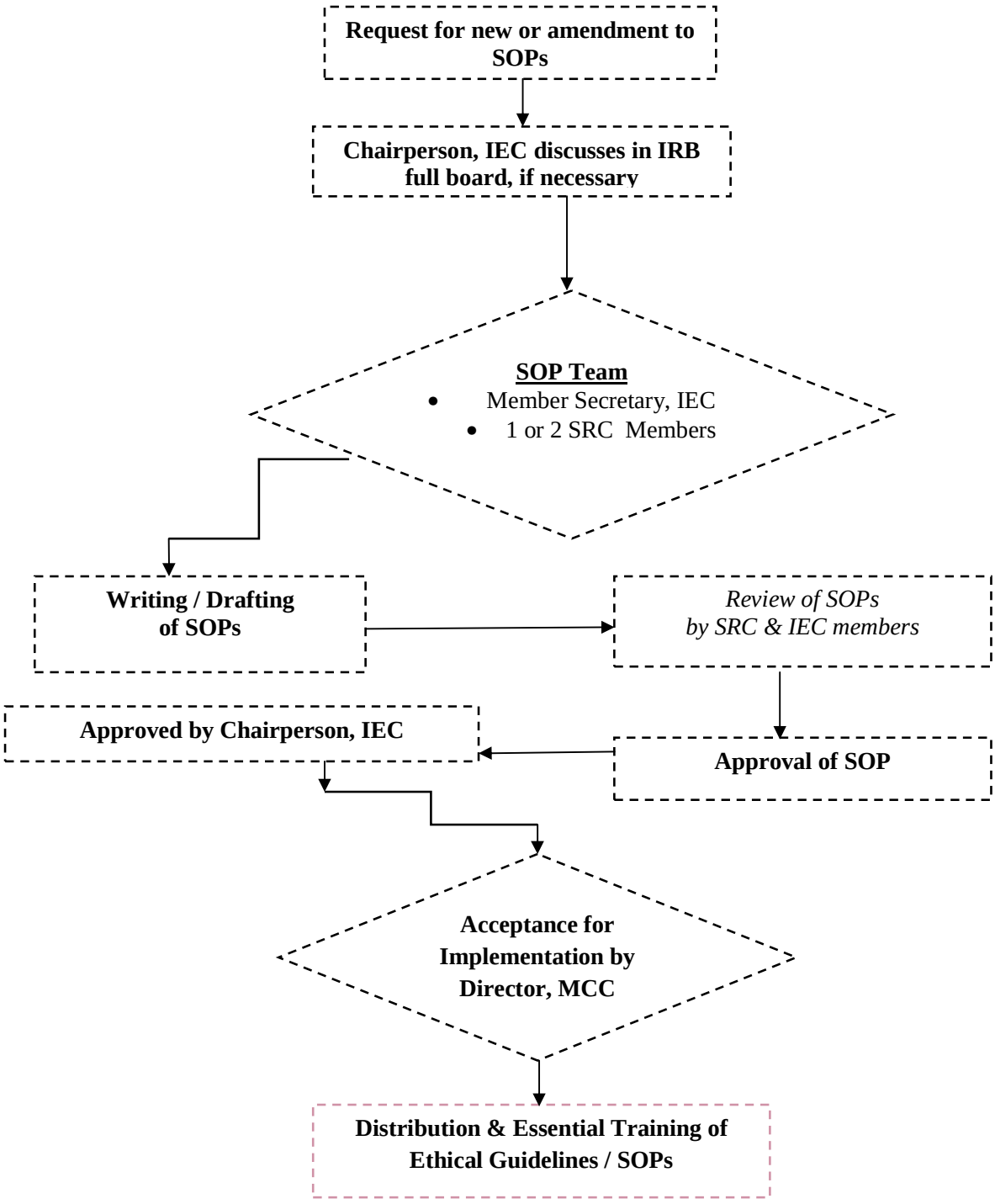
ANX6-VER1/SOP01/VER1

Log of SOPs Recipients

(Other than IRB-SRC & IRB-IEC members)

Serial No.	Name of the Recipient	Designation	SOP Code No..	No. of Copies	Signature With Date
1	XXXX	XXXX			
2	XXXX	XXXX			
3					
4					
5					

FLOW CHART


Request for new or amendment to SOPs
Chairperson, IEC discusses in IRB full board, if necessary
SOP Team
Member Secretary, IEC
1 or 2 SRC Members
Writing / Drafting of SOPs
Review of SOPs by SRC & IEC members
Approved by Chairperson, IEC
Approval of SOP
Acceptance for Implementation by Director, MCC
Distribution & Essential Training of Ethical Guidelines / SOPs