



IHEC – MGMCRI SOPs
Preparation of Standard Operating Procedures
for Institutional Human Ethics Committee
(IHEC), MGMCRI

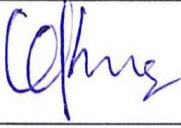

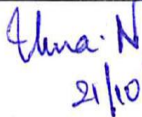

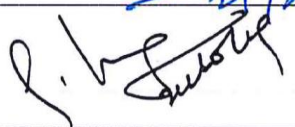
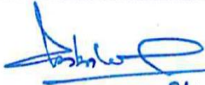


SOP Code: SOP 01/V2
Effective from 21/10/2019

Title: Preparation of Standard Operating Procedures for Institutional Human Ethics Committee (IHEC), MGMCRI

SOP Code: SOP 01/V2

Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
Dr. Lokesh. S, IHEC Member	 21/10/19
Dr. Siva Ranganathan Green, Member Secretary, IHEC	 21/10/19
Dr. Uma Narayanamurthy, Additional Member Secretary, IHEC	 21/10/19
Reviewed by:	Signature and Date:
Dr. Ananthakrishnan. N, IHEC Member	 21/10/19
Dr. Sivagnanam G, IHEC Co-Chairperson	 21/10/19
Approved by:	Signature and Date:
Dr. Jambulingam, P IHEC Chairperson	 21.10.19
Dr. Adithan C, Dean Research, SBV	 21/10/19
Dr. Ravishankar M, Dean, MGMCRI	 21/10



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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the process for writing, reviewing, distributing and amending SOPs of the Institutional Human Ethics Committee (IHEC), MGMCRI. The SOPs provides clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IHEC, MGMCRI.

3. Responsibility

It is the responsibility of the Chairperson of the IHEC to appoint SOP team to formulate new SOPs or to revise existing SOPs. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the IHEC.

3.1 Secretariat of the IHEC will

- Assist Chairperson to formulate an SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Ensure that all the IHEC members and involved administrative staff have access to the SOPs
- Ensure that all the IHEC members and involved staff are working according to current version of SOPs
- SOPs will be uploaded in the IHEC website which can be accessed by all PIs.

3.2 SOP team will

- assess the request(s) for SOP/s revision in consultation with the Secretariat, Member Secretary/Additional Member Secretary and Chairperson
- propose new / modified SOP/s as needed
- draft the SOP/s in consultation with the IHEC members and involved administrative staff
- review the draft SOP



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- To submit the draft for approval to Chairperson and Dean MGMCRI.

3.3 Chairperson of the IHEC will

- appoint one SOP Team
- approve the SOPs
- Sign and date the approved SOPs

3.4 IHEC

- members will sign and date the approved SOP when they receive it
- administrative staff will maintain a file of all SOPs received


4. Detailed instructions

4.1 Identify the need for new or amendment of current SOP

Any member of IHEC or Secretariat who would feel the requirement of a revision or notices an inconsistency/ discrepancy/ has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his/ her request by writing to the IHEC Chairperson either as an email/ letter/ verbal request in a meeting. The chairperson will inform all the IHEC members about this request at a regular full-board IHEC meeting. If the IHEC members agree to the request, an appropriate SOP team(s) will be appointed by the chairperson and designates the task to proceed with the revision process/ formulation process of the SOP. If the IHEC members do not agree, no further action will be taken. The Chairperson will inform the decision to the Members of the IHEC.

4.2 Appoint the SOP Team(S)

- The Chairperson will constitute an SOP Team(s) consisting of the Member Secretary/Additional Member Secretary and two or more members of the IHEC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections 4.3-4.7.


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4.3 Write all relevant procedures

- Write down step by step all the procedures of the IHEC that are to be standardized in the form of an SOP
- Organize, divide and name each process

4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.
- Each SOP should be given a number and title that is self-explanatory and easily understood. A unique code number with the format SOP xx/Vy will be assigned to each SOP item by the Secretariat. “xx” will be a two-digit number assigned specifically to each activity based SOP. “V” refers to version of SOP and “y” will be a number identifying the version. The first SOP of the current version would be SOP 01/V1 i.e. it is SOP number 01 with version 1.
- Each SOP may have annexures which are forms to be filled in by various stakeholders [IHEC or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form, pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example AX 01/SOP01/V2 means annexure form number 1 belonging to SOP 01/V2.
- Each SOP will be prepared according to the standard template in AX 01/SOP01/V2. Each page of the SOP will bear the header which will have the effective date of approval by the Chairperson. The SOP number will be on the right hand corner with the title of the SOP while the footer will bear the page number as page p of q (total) pages
- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by

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the SOP team members; a copy of the revised draft SOP will be sent to the Member-Secretary/Additional Member Secretary, who will circulate it to all the IHEC members.

4.5 Write and review a revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (AX 02/SOP01/V2) along with description of the main change/s.
- The rest of the steps are as described in **Section 4.4**.

4.6 Prepare and submit final draft

- The SOP Team will submit the reviewed SOP to the IHEC Members who will review it at a meeting.
- The suggestions that are agreed upon by the IHEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team will continue to exist until the tenure of the IHEC or until the next team takeover.

4.7 Approve the new / revised SOP

- The final version after approval by the SOP Team will be presented to the Chairperson.
- The authors, reviewers and chairperson will sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from which the SOP will be implemented. The front page may also contain signature of Chairperson of IHEC and Dean MGMCRI as having approved the document.

4.8 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary/Additional Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- The approved SOP will be distributed to the IHEC members and a log will be maintained as per the annexure – AX 03/SOP 01/V2.



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- One complete original set of current SOP will be filed in the SOP Master file, by IHEC Secretariat in the IHEC office.
- When the revised version is distributed, all the IHEC members will be requested to destroy their earlier version. Only one copy of earlier version will be filed in the file entitled ‘Past SOPs of IHEC’ by IHEC Secretariat in IHEC office.
- The IHEC members and secretariat will review SOPs at least once in every 3 years/whenever regulatory guidelines are revised.

5. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IHEC 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.
IHEC Members	Individuals serving as regular members of the Institutional Human Ethics Committee. The Board has been constituted in accordance with the IHEC membership requirements set forth in New Drug and Clinical Trial approval regulations 2019 dated 19 March 2019 GSR-227-E and ICMR 2017.
SOP Team	A Team of members selected from the Institutional Human Ethics Committee including the Member Secretary and at least two more members who oversee the creation, preparation, review and periodic revision of the Institutional Human Ethics Committee SOPs.
Master SOP files	An official collection of the Standard Operating Procedures (SOPs) of Institutional Human Ethics Committee accessible to all staff, IHEC/ members, auditors and government inspectors as a paper copy with an official stamp and the signature of either member secretary/ chairperson of the IHEC on the first and the last page of the SOP booklet. Photocopies made from these official paper versions of the SOP cannot be considered official.
Past SOPs of the IHEC	A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations.
Effective date	The date of approval of the SOPs signed and dated by the Institutional Human Ethics Committee- Chairperson and subsequently the SOP is implemented from that date.

6. Annexures

Annexure 1 AX 01/SOP 01/V2 Template for SOPs

Annexure 2 AX 02/SOP 01/V2 Documentation of History of the SOPs

Annexure 3 AX 03/SOP 01/V2 Log of the IHEC members receiving SOPs

Annexure 4 AX 04/SOP 01/V2 List of SOPs of the IHEC



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Annexure 1: AX 01/SOP 01/V2

Template for Standard Operating Procedures

Logo of institution (if necessary)	Institutional Human Ethics Committee Title of the SOP	SOP Code: SOP xx/yy Effective date: aa/bb/cc
<p>Title: Title which is self-explanatory and easily understood</p> <p>SOP Code: SOP xx/yy</p> <p>Effective date: aa/bb/cc</p> <p>Prepared by:</p> <ul style="list-style-type: none"> • XXXXXXXXXXXXXXXX • XXXXXXXXXXXXXXXX <p>Reviewed by:</p> <ul style="list-style-type: none"> • XXXXXXXXXXXXXXXX • XXXXXXXXXXXXXXXX <p>Approved by:</p> <ul style="list-style-type: none"> • XXXXXXXXXXXXXXXX • XXXXXXXXXXXXXXXX 		
<p style="text-align: right;">Signature with date: _____</p> <p style="text-align: right;">Signature with date: _____</p> <p style="text-align: right;">Signature with date: _____</p> <p style="text-align: right;">Signature with date: _____</p> <p style="text-align: right;">Signature with date: _____</p> <p style="text-align: right;">Signature with date: _____</p>		
Page No.: p q		

Main Text:

1. **Purpose:** Summarized and explains the objectives of the procedure
2. **Scope:** Stated the range of activities that the SOP applies to.
3. **Responsibility:** Refers to person(S) assigned to perform the activities involved in the SOP
4. **Detailed instructions:** Describes procedures step by step in short and clear sentences
5. **Annexure:** Forms to capture information pertaining to the SOP instructions
6. **Flow chart:** simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.

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Annexure 2: AX 02/SOP 01/V2
Documentation of History of the SOPs


Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main changes/s
1. Prof. Lokesh S 2. Prof. Ananthkrishnan 3. Prof. Reba Kanungo	V1	01/10/2017	SOP prepared according to ICMR guideline 2017
1. Dr. Lokesh S 2. Dr. Siva Ranganathan Green 3. Dr. Uma Narayanamurthy 4. Dr. Ananthkrishnan 5. Dr. Sivagnanam G 6. Dr. Jambulingam 7. Dr. Adithan C 8. Dr. Ravishankar M	V2	21/10/2019	SOP amendments and modifications done after SIDCER survey in accordance with the present national and international technical and ethical guidelines in human research

Annexure 3: AX 03/SOP 01/V2

Log of the IHEC members receiving SOPs

No.	Name of Recipient	Designation	SOP code number	No. of Copies	Signature	Date

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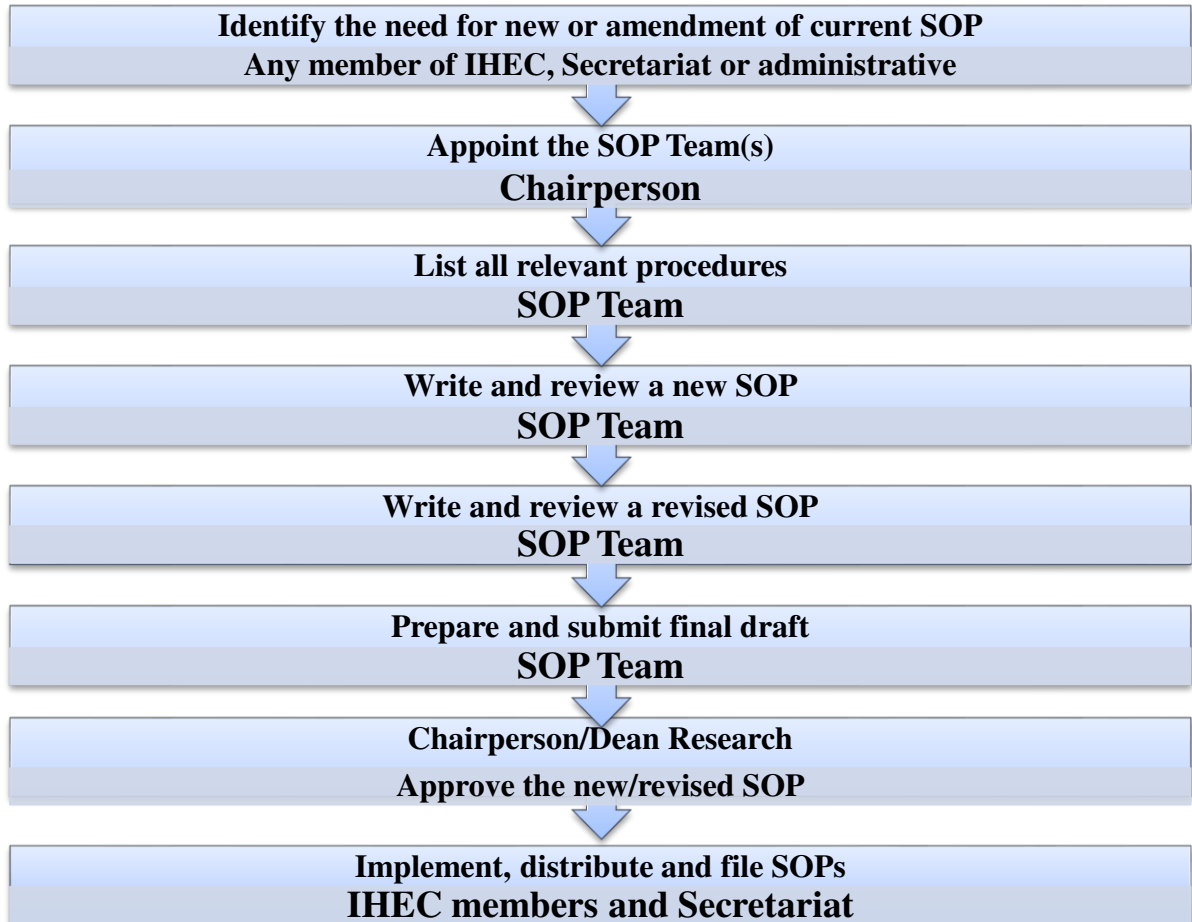
Annexure 4: AX 04/SOP 01/V2

List of SOPs of the Institutional Human Ethics Committee

S. No.	Title of the Standard Operating Procedures (SOPs)	SOP No.
1	<i>Preparation of Standard Operating Procedures for Institutional Human Ethics Committee</i>	SOP 01
2	<i>Constitution of Institutional Human Ethics Committee (IHEC), Selection, Roles and Responsibilities of Members of the IHEC</i>	SOP 02
3	<i>Handling Conflict of Interest among Ethics Committee Members</i>	SOP 03
4	<i>Selection and Responsibilities of Independent Consultants</i>	SOP 04
5	<i>Procedures for allowing Guest/ Observer to visit Institutional Human Ethics Committee or attend IHEC meeting</i>	SOP 05
6	<i>Management of Submission of Research Study Protocol and Study Related Documents</i>	SOP 06
7	<i>Categorization of New Research Study Protocols for Initial Review</i>	SOP 07
7A	<i>Full Board Review of New Research Study Protocols</i>	SOP 7A
7B	<i>Expedited Review of Research Study Protocols</i>	SOP 7B
7C	<i>Exemption from Ethics Review of Research Study Protocols</i>	SOP 7C
8	<i>Agenda Preparation, Meeting Procedures and Recording of Minutes</i>	SOP 8
9	<i>Review of Resubmitted and Amended Protocols and Protocol-related Documents</i>	SOP 9
10	<i>Continuing Review of Study Protocols</i>	SOP 10
11	<i>Review of Protocol Deviations / Violations</i>	SOP 11
12	<i>Review of Serious Adverse Event (SAE)</i>	SOP 12
13	<i>Review of Study Completion Reports</i>	SOP 13
14	<i>Management of Premature Termination / Suspension / Discontinuation of the Study</i>	SOP 14
15	<i>Waiver of Written/ Verbal Informed Consent</i>	SOP 15
16	<i>Site Monitoring and Post Monitoring Activities</i>	SOP 16
17	<i>Dealing with Participant's Requests and/or Complaints to Institutional Human Ethics Committee</i>	SOP 17
18	<i>Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents</i>	SOP 18
19	<i>Reviewing Proposals Involving Vulnerable Populations</i>	SOP 19
20	<i>Preparation for Audit / Inspection</i>	SOP 20
21	<i>Training and Assessment of Institutional Human Ethics Committee Members</i>	SOP 21



7. Flow Chart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*