



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of Independent Ethics Committee, Mumbai. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005), ICMR's Ethical Guidelines for Biomedical Research on Human Participants (2006), Indian GCP Guidelines (2001), WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research (2000) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996).

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Independent Ethics Committee, Mumbai (IEC).

3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint the SOP Team to formulate the SOPs. The SOP Team shall do this by following the same procedures, format, and coding system when drafting or editing any SOP of the Independent Ethics Committee.

3.1 Secretariat of Independent Ethics Committee, Mumbai will

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed
- Distribute the SOPs with a receipt to all users
- Ensure that all IEC members and involved administrative staff have access to the SOPs
- Ensure that all IEC members and involved staff are working according to current version of SOPs
- Maintain on file all past SOPs of Independent Ethics Committee, Mumbai
- Assist Chairperson to formulate an SOP Team



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

3.2 SOP team (will contain Member Secretary and at least two other members) will:

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose new/ modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

3.3 Chairperson of the IEC will:

- Appoint the SOP Team
- Approve the SOPs
- Sign and date the approved SOPs

3.4 Ethics committee members and involved administrative staff will:

- Sign and date the approved SOP when they receive it
- Maintain a file of all SOPs received
- Return all out-of-date SOPs to the Secretariat

4. Flow Chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Identify the need for new or amending SOP	Any member of IEC
2	Appoint the SOP Team	Chairperson
3	List all relevant SOPs	SOP Team
4	Design a format and layout	SOP Team
5	Write and review a new/revised SOP	SOP Team
6	Review by consultation	SOP Team and all IEC members



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
7	Preparation and submission of final draft	SOP Team
8	Approve a new/revised SOP	Chairperson
9	Ensure implementation, distribute and file all SOPs	IEC members and Secretariat
10	Review and request for a revision of existing SOPs	IEC members/ Administrative staff/Chairperson
11	Manage current and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Identify the need for new or amending SOP

Any member of the IEC, Secretariat or administrative staff who would like 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 request by using the Request for Formulation of new SOP/ Revision of an SOP Form *AF/05/01-SOP01/01* to make a request. This annex form is submitted to the IEC Chairperson.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team will be appointed by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, the Chairperson will inform the person/ IEC member who made the request for modification of the SOP in the same meeting.

5.2 Appoint the SOP Team

The Chairperson will identify appropriate members of the IEC who have a thorough understanding of the ethical review process to constitute the SOP writing team. The SOP writing team will carry out the subsequent steps. (5.3-5.7)



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

5.3 List all relevant SOPs

- Write down step by step all the procedures of Independent Ethics Committee, Mumbai.
- Organize, divide and name each process
- Make a list of SOPs with coding reference (*AF/01/01-SOP01/01*)

5.4 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format

SOP xx / yy

will be assigned to each SOP item by the Secretariat.

xx will be a two-digit number assigned specifically to that SOP.
yy will be a two-digit number identifying the version of the SOP

The number of version should be started from 01 hence for example, SOP01/01 is the SOP number 01 with version 01.

Each annex will be given unique code number with the format *AF/BB/CC-SOP xx/yy*.

AF refers to Annex Form, BB is a two-digit number identifying the number of the annex, CC is a two digit number identifying the version of the annex form while xx refers to the SOP number, yy refers to versions for example *AF/01/01-SOP01/01* means Annex Form number one with version one belonging to the SOP 01/01

Each SOP will be prepared according to the standard template in *AF/02/01-SOP01/01*. Each page of the SOP will bear the header which will have the effective date i.e. the date of approval of the SOPs signed and dated by the Independent Ethics Committee Chairperson and subsequently the SOP is implemented from that date. The SOP number on the left hand corner while the right hand corner will bear the page number as Page—of---total pages.



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

5.5 Write and review a new/revised SOP

- If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the Document History Form *AF/03/01-SOP01/01*.
- When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team, appointed by the Chairperson.

5.6 Review by Consultation

- The draft SOP written by one / two members of the SOP team will be reviewed by the other two of the IEC members who form the SOP team. After incorporating the suggestions put forth by the SOP team members; the copy of the revised draft SOP will be circulated to all the other IEC members.

5.7 Preparation and submission of final draft

- All the members will review the revised draft SOP.
- In the regular full board meeting all the members can put forth their suggestions / comments on the revised draft SOP.
- The suggestions agreed upon unanimously, by all the IEC members will be incorporated in the revised draft SOP and the final draft SOP will be formulated.

5.8 Approve a new/ revised SOP

- The final version will be presented to the Chairperson for review and approval.
- The Chairperson signs and dates the SOP on the first and last page of the SOP document. This date of approval is declared as the effective date from where by the SOP is implemented.
- The SOP should be agreed upon by the people involved in that particular task and all the Independent Ethics Committee members.

5.9 Ensure Implementation, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The Secretariat will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- The approved SOPs will be distributed to the IEC members and the relevant staff by the Secretariat according to the distribution list. (*AF/04/01-SOP01/01*).



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

- When the revised version is distributed, the old version will be retrieved from all the Independent Ethics Committee members, relevant staff and destroyed except for one copy.
- This copy of the earlier version will be placed in the file entitled 'Past SOPs of Independent Ethics Committee, Mumbai'
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat of the IEC in the office of Independent Ethics Committee, Mumbai.

5.10 Review and request for a revision of existing SOPs

- Any member of the IEC, Secretariat or administrative staff who would like a revision or notices an inconsistency or has any suggestions on how to improve a procedure should use the form *AF/05/01-SOP01/01* to make a request.
- If the IEC members agree to the request, an appropriate SOP team will be designated to proceed with the revision process. If the IEC members do not agree, the Chairperson will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as a new SOP (Section 5.6, 5.7, 5.8).
- The Secretariat is expected to review the SOPs at least every 2 years and record the dates of review on the SOP Master file.

5.11 Manage current and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked "superseded" and archived in the file entitled 'Past SOPs of Independent Ethics Committee, Mumbai' by the Secretariat.

6. Glossary

SOP
(Standard Operating
Procedure)

Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC 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.



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

IEC members	Individuals serving as regular members of the Independent Ethics Committee, Mumbai. The Committee has been constituted in accordance with the EC membership requirements set forth in Schedule Y (20 th January 2005)
SOP Team	A Team of members selected from the Independent Ethics Committee, Mumbai including the Member Secretary and at least two more members who oversee the creation, preparation, review and periodic revision of the Independent Ethics Committee, Mumbai SOPs.
Master SOP files	An official collection of the Standard Operating Procedures (SOP) of Independent Ethics Committee, Mumbai accessible to all staff, IEC/ members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.
Effective date	The date of approval of the SOPs signed and dated by the Independent Ethics Committee Chairperson and subsequently the SOP is implemented from that date.

7. References

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 24 March 2008)
3. ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)- http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 24 March 2008)
4. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) [http://www.cdsco.nic.in/html/Schedule-Y%20\(Amended%20Version-2005\)%20original.htm](http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm) (last accessed 24 March 2008)



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

8. Annexure

ANNEX 1	AF/01/01-SOP01/01	List of SOPs of Independent Ethics Committee, Mumbai
ANNEX 2	AF/02/01-SOP01/01	Template for Standard Operating Procedures
ANNEX 3	AF/03/01-SOP01/01	Document History of the SOP
ANNEX 4	AF/04/01-SOP01/01	Log of SOP Recipients
ANNEX 5	AF/05/01-SOP01/01	Request for Formulation of new SOP/ Revision of an SOP



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

Annex 1
AF/01/01-SOP01/01

List of SOPs of Independent Ethics Committee, Mumbai

Serial No.	Title of the Standard Operating Procedures (SOPs)	SOP Code
1	Preparing Standard Operating Procedures (SOPs) for the Independent Ethics Committee (IEC).	SOP 01/01
2	Standard Operating Procedures for Constituting the Independent Ethics Committee.	SOP 02/01
3	Standard Operating Procedures for Confidentiality / Conflict of Interest Agreements	SOP 03/01
4	Standard Operating Procedures for Selection and Responsibilities of Independent Consultants	SOP 04/01
5	Standard Operating Procedures for Management of Protocol Submissions	SOP 05/01
6	Standard Operating Procedures for Initial Review of Submitted Protocol	SOP 06/01
7	Standard Operating Procedures for Projects Submitted to Expedited Review	SOP 07/01
8	Standard Operating Procedures for Review of Resubmitted Protocols	SOP 08/01
9	Standard Operating Procedures for Review of Amended Protocol/Protocol related documents	SOP 09/01
10	Standard Operating Procedures for Continuing Review of Study Protocols	SOP 10/01
11	Standard Operating Procedures for review of Study Completion Reports	SOP 11/01
12	Standard Operating Procedures for Protocol Deviation/Non-Compliance/Violation	SOP 12/01
13	Standard Operating Procedures for Management of Premature Termination of the Study	SOP 13/01
14	Standard Operating Procedures for Review of Serious Adverse Event (SAE) Reports	SOP 14/01



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

Serial No.	Title of the Standard Operating Procedures (SOPs)	SOP Code
15	Standard Operating Procedures for Site Monitoring Visit	SOP 15/01
16	Standard Operating Procedures for Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 16/01
17	Standard Operating Procedures for Conduct of Emergency Meeting	SOP 17/01
18	Standard Operating Procedures for Maintenance of Active Project Files	SOP 18/01
19	Standard Operating Procedures to Archive and Retrieve Documents	SOP 19/01
20	Standard Operating Procedures for Maintaining Confidentiality of IEC Documents	SOP 20/01



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

Annex 2
AF/02/01-SOP01/01

Template for Standard Operating Procedures

Independent Ethics Committee, Mumbai	
Title:	<i>Title which is self-explanatory and is easily understood</i>
SOP No:	<i>SOPxx/yy</i>
Page:	? Of ?

TITLE <i>Title which is self-explanatory and is easily understood</i>

Effective Date:	
Supersedes:	
Author: (Name).	Date:.....
Approved by: (Name)	Date

Table of CONTENTS

1	Purpose
2.	Scope
3.	Responsibility
4.	Flow chart
5.	Detailed instructions
6	Glossary
7	References
8	Annexure



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

Main Text:

1. **Purpose** - *summarizes and explains the objectives of the procedure.*
2. **Scope** – *states 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. **Flow chart** – *simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*
5. **Detailed instructions** – *describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*
6. **Glossary** – *clarifies uncommon or ambiguous words or phrases by explanation.*
7. **References** – *lists sources of the information given in the SOP*
8. **ANNEX** - *documents that explain further or clarify complex descriptions. “Description-by-example” is always recommended to avoid difficult texts which may be hard to understand*



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.S.D

Annex 4
AF/04/01-SOP01/01

Log of SOP Recipients

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date
1	Dr.R.D.Lele	Chairperson				
2	Dr.Raakhi Tripathi	Member Secretary				
3	Dr.R.B.Pandit	Associate Member Secretary				
4	Dr.U.M.Thatte	Member				
5	Dr.D.N.Upasani	Member				
6	Dr.R.K.Sharma	Member				
7	Dr.Sandhya Kamat	Member				
8	Dr.Sandeep Bavdekar	Member				
9	Ms.Nruta Vasudev	Member				
10	Rev Jonah David	Member				
11	Ms.Kanchan M Patil	Member				



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

Annex 5
AF/05/01-SOP01/01

Request for Formulation of new SOP/ Revision of an SOP

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

<i>SOP 01/01</i>	
Title:	
Details of problems or deficiency in the existing SOP	
Need to formulate an entirely new SOP (i.e. SOP not existing previously)	
Identified by:	Date (D/M/Y):
Discussed in Independent Ethics Committee Meeting held on :-	
SOP revision required:	<input type="checkbox"/> Yes <input type="checkbox"/> No
New SOP to be formulated:	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, to be carried out by whom?	
If no, why not?	
Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	