Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Ethics Committee (EC), M S Ramaiah Medical College and Hospitals.

SOP Number	EC SOP 01/V 11
Effective Date	28 May 2019
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Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
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Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K. Sreedhar Rao (Chairman-EC)	K Sreedhar 28/5/2019

Table of Contents:

1. **Purpose**

   This SOP defines the process for writing, reviewing, distributing, and amending Standard Operating Procedures (SOPs) within the Ethics Committee (EC), M S Ramaiah Medical College and Hospitals (MSRMCH). The SOPs will provide clear, unambiguous instructions to conduct activities of the EC in accordance with the current ICMR guidelines, New Drugs and Clinical Trials Rules, 2019, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, ICH (International Conference on Harmonization) Good Clinical Practice (GCP) and Indian GCP.

2. **Scope**

   This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the EC, MSRMCH.

3. **Responsibility**

   It is the responsibility of Chairman and Member Secretary to direct Secretary, EC to formulate/ amend the EC SOP as and when required in compliance with national regulation. Secretary, EC will draft the SOP and will get it reviewed by the EC Member Secretary. All members of EC will review the SOPs and final approval and sign will be done by Chairman of EC.

4. **Detailed Instruction**

4.1. Identify the need for new or revision of existing EC SOP and delegating the responsibility:

- The regular review and revision (if required) of the EC SOP will be done once every three years.
- Any member of the EC, Secretary or administrative staff who notices that current SOPs have some lacunae or notice an inconsistency/ discrepancy or have any suggestions to improve a procedure can make a written/verbal request to EC Chairman/ Member secretary.
- The Chairman will inform all EC members about this request in a regular full board meeting and if the members agree to the request, the Chairman will designate the Secretary, EC to proceed with the task of revision/formulation process of the SOP. Only regular members shall participate in decision making regarding accepting or rejecting the proposed amendment.
- If the Committee does not agree, no further action will be taken, however the Chairman will inform the concerned individual who made the request for revision.
- If only few section of the EC SOP need revision (before the scheduled full EC SOP revision), to be in line with regulatory requirement, then an addendum can be created for the existing SOP for that particular section. The same will be considered as Addendum to the EC SOP from the effective date and will supersede the previous version until the full EC SOP is revised as per the schedule and the details of previous SOP version will be indicated in the Document history Form (AX 02-EC SOP 01/V11) mentioned before table of contents.
- Chairman will delegate the Secretary, EC to prepare and Member Secretary to review and circulate to all the members for their inputs and suggestions.

4.2. Relevant list of SOP:

- Write down step by step all the procedures of the EC SOP or for the section which requires amendment. Organize, devise and name each process and make a relevant list of the contents of the SOP with coding format. A list of SOPs will be maintained along with EC SOP as per AX 04- EC SOP 01/V 11

4.3. Design a format and layout:

- Each SOP should be given a number and a title that is self-explanatory and is easily understood. The table of content should have all the title and SOP number with page number.
- Each SOP should be given a unique number and effective date, with the format EC SOP xx/V yy and DD MMM YYYY respectively. "xx" is a two-digit number assigned to a specific SOP in sequence, "V" refers to version of the SOP and "yy" is a two-digit number identifying the version in sequence e.g. EC SOP 01/V 04 is SOP number 01 with version no.04.
- The EC SOP addendum will be numbered with respect to the main SOP as EC SOP xx/V yy addendum yy.zz and effective date as DD MMM YYYY, where "zz" is a two-digit number identifying the addendum in sequence e.g. EC SOP 01/V 04 addendum 04.01 is SOP number 01 with version no.04 and addendum 04.01.
- Each Annexure (AX) is unique code with format AX nn- EC SOP xx/V yy. E.g. AX 01- EC SOP 01/V 04 indicates AX is Annexure, 01 is Annexure no., belonging to the EC SOP 01/V 04.
- The first page of each SOP document will be on letter head and will be signed and dated by the author of the SOP, the EC Member Secretary who has reviewed the SOP, and EC Chairman who has approved and subsequently the SOP will be implemented from that date (AX 01- EC SOP 01/V 10). The second page will have table of content of that particular SOP with page numbers. All the remaining pages will be on plain sheets with EC seal.
- Except the first page of SOP which will be on letter head, each page will bear a header with the SOP number, effective date which is the date of approval of the SOP. The SOP title will be on the left hand corner of the footer while the right hand corner of the footer will bear the page number as Page__of__(total pages).
- SOP formatting
  - The text section is numbered using a standard format.
  - Define job titles or unusual terms the first time they appear, followed by the abbreviation in parentheses.
  - Write the numbers 1 through 9 in words within the text. Write the numbers 10 and greater in the numerical form.
- Maintain a historical archive of copies of all previous versions of SOPs to be available in the event of an audit. The history of evolution of previous SOPs of the EC will be documented in the SOP.
- Write the SOP, preferably using the following sections however additional sections can be added as necessary:
  - Introduction or Purpose: Defines the general area and explains the objective the SOP is intended to achieve.
  - Scope: State the range of activities the SOP applies to, as well as any limitations or exceptions.
  - Responsibility: Indicates those within the committee responsible for each identified SOP activity.

- Definitions, if any.
- Procedures: describes instructions for common procedures conducted within the scope of the SOP in simple steps.
- Additional references, if any.

4.4. Write, Review and Submission of final draft SOP:

- With reference to above guideline the draft SOP will be prepared by the Secretary, EC.
- The draft SOP will be circulated and discussed with the Member Secretary and members of EC. Members can put forth their suggestions / comments on the draft revised SOP. The suggestions agreed upon unanimously by all EC members will be incorporated and the final draft SOP will be formulated.
- The final version will be forwarded to the Chairman for review and approval.

4.5. Final Approval of new or revised SOP:

- The Chairman will sign and date the first page of each SOP. This date of approval is declared as the effective date for implementing the SOP.
- SOP addendum will be reviewed and approved in the same manner as new SOPs.

4.6. Implement, distribute and file all SOP's :

- Approved SOPs will be implemented from the effective date.
- A training record will be maintained for all the EC members for the new EC SOP.
- When a revised version is distributed (AX 03- EC SOP 01/V 11), the old version will be retrieved from all members and destroyed.
- The complete original set of current SOP will be archived in the SOP master file by the Secretary, EC and maintained in the EC office. Photocopies made from this official paper versions of the SOP can be considered current.
- Member Secretary, Chairman and Secretary, EC will ensure that the EC members and involved staff have access to the SOP and are working according to current version of SOP.

4.7. Manage and archive superseded SOP's:

- Old SOP's should be retained and clearly marked "superseded" and archived in the master file by the Secretary, EC. The process of evolution of previous SOPs of the EC will be documented in the EC SOP file.

5. References used for preparing SOP:

- World Health Organization. Operational Guidelines for Ethics Committee That Review Biomedical Research, 2011.
- World Medical Association. Declaration of Helsinki. 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
- The Nuremberg Code.

- Council of International Organizations of Medical Science (CIOMS). International guidelines for Ethical Review of Epidemiological Studies, Geneva 2016.
- Ethical Guidelines for Biomedical research on Human Participants, ICMR guidelines.
- Good Clinical Practices for clinical Research in India Amended Version 2005, issued by CDSCO, India.
- Guideline for Good Clinical Practices E6 (R2)- International Council on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (Step 4 Version dated 09 Nov 2016)
- Drugs and Cosmetics (First Amendment) Rules, 2013. G.S.R.53(E) dated 30 Jan 2013 (inserting Rule 122DAB- Compensation in case of death or injury during clinical trials).
- Drugs and Cosmetics (Second Amendment) Rules, 2013. G.S.R.63(E) dated 01 Feb 2013 (inserting Rule 122 DAC- Permission to conduct Clinical Trials).
- Drugs and Cosmetics (Third Amendment) Rules, 2013. G.S.R.72(E) dated 08 Feb 2013 (inserting Rule 122 DD- Registration of Ethics Committee).
- Drugs and Cosmetics (Fifth Amendment) Rules, 2013. G.S.R.611(E) dated 31 Jul 2015 (inserting requirement of Audio Video recording of Informed consent process and addition in essential elements of Informed consent).
- Drugs and Cosmetics (Sixth Amendment) Rules, 2013. G.S.R.889(E) dated 12 Dec 2014 (inserting New DCGI SAE reporting timeline and Compensation criteria).
- New Drugs and Clinical Trials Rules, 2019. G.S.R.227(E) dated 19 Mar 2019.
- FERCI Guideline http://ferci.org/sops

AX 01- EC SOP 01/V 11

Template for Standard Operating Procedures

Ethics Committee, M S Ramaiah Medical College and Hospitals	
Title: *Title which is self-explanatory and is easily understood*	
SOP No:	EC *SOP xx/V yy*
Effective date:	DD/MMM/YYYY
No of pages	a to b
Superseded Version Number & Date	V xx & DD/MMM/YYYY
Author: **Name, designation, sign and date**: xxxxxxxxx **Reviewed by**: **Name, designation, sign and date**: xxxxxxxxx **Approved by**: **Name, designation, sign and date**: xxxxxxxxx	

Tables of Contents

Main Text:

AX 02- EC SOP 01/V 11

Document History Form for Addendum

Sl. No.	Description of Change	Version/ Date(dd-mmm-yyyy)	Addendum Version/ Date(dd-mmm-yyyy)
01			
02			
03			

AX 03- EC SOP 01/V 11

Log of the EC Members receiving SOPs

Sl. No.	Name of Recipients	Designation	SOP No	No. of Copies	Signature	Date
1	XXXXX	Chairman				
2	XXXXX	Member Secretary				
3	XXXXX	Member				

AX 04- EC SOP 01/V 11

List of SOPs of Ethics Committee

SL.NO	TITLE OF STANDARD OPERATING PROCEDURE	SOP No
1	Preparing Standard Operating Procedures (SOPs)- Writing, Reviewing, Distributing & Amending SOPs for the Ethics Committee, M S Ramaiah Medical College and Hospitals	EC SOP 01/V 11
2	Constitution of Ethics Committee, M S Ramaiah Medical College & Hospitals	EC SOP 02/V 11
3	Application Procedure	EC SOP 03/V 11
4	Review Procedure	EC SOP 04/V 11
5	Ethics Committee Meeting- Agenda Preparation, Meeting Procedures, Decision Making, Recording of Minutes, Communicating the decision and Activity Report	EC SOP 05/V 11
6	Review of Amended protocol/ Protocol related documents	EC SOP 06/V 11
7	Continuing Review of Study Protocols	EC SOP 07/V 11
8	Review of Serious Adverse Event	EC SOP 08/V 11
9	Review of Protocol Deviation/Non-Compliance/ Violation/ negligence	EC SOP 09/V 11
10	Review of requests & complaints from participants / patients and other stake holders	EC SOP 10/V 11
11	Record keeping and Archiving- Maintenance of Documents of Ethics Committee activity, Active study files, Archival, Dispose of closed files and retrieval of documents	EC SOP 11/V11
12	Site Monitoring	EC SOP 12/V 11
13	Studies involving vulnerable population	EC SOP 13/V 11
14	Ethics Committee: Fee Structure For Protocol Review	EC SOP 14/V 11

AX 05- EC SOP 01/V 11

List Of Acronyms

Acronym		Full Title/Description
AIDS	:	Acquired Immuno Deficiency Syndrome
AE	:	Adverse Event
BA/BE	:	Bioavailability/Bioequivalence
CE	:	Chief Executive
CFR	:	Code of Federal Regulation
CIOMS	:	Council for International Organizations of Medical Sciences
COI	:	Conflict Of Interest
Co-I	:	Co Investigator
CRF	:	Case Record Form
CRO	:	Clinical Research Organization
CSR	:	Clinical Study Report
DCGI	:	Drug Controller General of India
DSMB	:	Data and Safety Monitoring Board
EC	:	Ethics Committee
ERB	:	Ethical Review Board
GCP	:	Good Clinical Practice
GEF	:	Gokula Education Foundation
HIV	:	Human Immunodeficiency Virus

IB	:	Investigator's Brochure
ICF	:	Informed Consent Form
ICH	:	International Committee for Harmonization
ICMR	:	Indian Council of Medical Research
IISc	:	Indian Institute of Science
IMS	:	International Medical School
MSRMCH	:	M S Ramaiah Medical College and Hospitals
NGO	:	Non-governmental organization
PI	:	Principal Investigator
Sub I	:	Sub Investigator
PD	:	Protocol Deviation
RISA	:	Ramaiah Indic Specialty Ayurveda
SAE	:	Serious Adverse Event
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Constitution of Ethics Committee, M S Ramaiah Medical College & Hospitals

SOP Number	EC SOP 02/V 11
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Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

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Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/2019

Table of Contents:

1. Introduction

- M S Ramaiah Medical College and Hospitals (MSRMCH) is one of the premier institute in the country and over the years its scientific rigor and research culture has led to a significant increase in the number of clinical trials being conducted. This gave rise to the need for a high quality, efficient and consistent ethical review mechanism for health and biomedical research to ensure the protection of human rights as mandated by Indian law.
- In lieu of the above, the Ethical Review Board (ERB) of MSRMCH was established by the Chief Executive, Gokula Education Foundation (Medical) (CE, GEF (M)) in the year 2000. The ERB reviews both, scientific and ethical aspects of the studies. Timely review and the safeguarding of high ethical standards formed the basis of the ERB review process.
- The Committee is constituted and is administratively governed by the Chief Executive, Gokula Education Foundation (Medical).
- The board will independently examine, scrutinize, review and oversee all the Clinical Trials/studies involving Pharmaceutical drug, devices, herbals or Ayurveda products, BA/BE studies, epidemiological, registry, observational and retrospective studies in addition to the academic studies of students and faculty involving patients/human participants proposed to be carried out in M.S. Ramaiah Medical College and Hospitals (which includes both M.S. Ramaiah Teaching Hospital & M.S. Ramaiah Memorial Hospital) and any other outside hospital or institution.
- Ethical Review Board was registered with Drug Controller General India (DCGI) and as the DCGI registration letter dated 20th Apr 2013 is in name of "Ethics Committee (EC), M S Ramaiah Medical College and Hospitals", the Ethical Review Board was renamed as "Ethics Committee, M S Ramaiah Medical College and Hospitals".
- EC is also registered with Office for Human Research Protections (OHRP) with Institutional Review Board (IRB) Organization registration no of IORG0006935.
- All the registrations are periodically renewed as required.
- The EC functions independently for maintaining a consistent scientific and ethical framework for patient care and research, and for integrating ethical values into practice, policy relationships and organizational activities.
- The purpose of the EC is to cultivate a pluralistic and democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of Institution.
- The mandate of the EC essentially is to promote patient care through a scientific and ethical approach to research and education.

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the frame work for constitution, selection, roles and responsibilities of the Institutional EC and procedure for maintaining confidentiality of all the activities and documents and to take care of conflict of interest.

3. Scope

The SOP applies to the formation of the EC, selection, roles and responsibilities of the members, maintaining confidentiality of all the activities and documents and to take care of conflict of interest

4. Responsibility

It is the responsibility of Chief Executive, Gokula Education Foundation (Medical) to constitute the Ethics Committee, in accordance to the requirement of New Drugs and Clinical Trials Rules, 2019, ICMR guideline, Indian GCP and ICH-GCP.

5. Detailed Instructions

5.1. Composition

- EC will comprise of 7 – 15 members to ensure a mandatory quorum of at least 5 members at each review meeting.
- One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by institute to maintain independence in functioning of the EC.
- One member who is affiliated with the institute shall be appointed as Member Secretary of the Ethics Committee by Institute.
- The EC will be multidisciplinary and multi-sectorial in composition including persons with relevant but diverse scientific expertise, who have the qualifications and experience to review and evaluate non-scientific, scientific and medical ethics aspects of research protocol.
- The EC will comprise of scientific and non-scientific members, clinicians and non – clinicians, clinical pharmacologist, a lawyer/expert in ethics, a social worker and layperson/patient representative to reflect the different viewpoints. The committee shall include at least one member whose primary area of interest or specialization is non-scientific and at least one member who is independent of the institution.
- The members are selected to have an equitable representation of all specialties in the institution and represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests with at least 50% of its members who are not affiliated with the institution or organization.
- In addition to the medical experts the Committee will have adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society.
- The EC should be constituted in the following pattern:-
  - Chairman
  - Member Secretary
  - Other members from medical, non-medical, scientific and non-scientific areas with at least one lay person, one women member, one legal expert and one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

5.2. Membership requirements and appointment:

- The Chairman, Member Secretary and member of the Ethics Committee are selected by the CE, GEF (M), as per New Drugs and Clinical Trials Rules, 2019, Indian GCP, ICH-GCP and other applicable regulatory guidelines and an order is issued to the Head of the Institution who will invite (AX 01- EC SOP 02/V 11), take their acceptance (AX 02- EC SOP 02/V 11) and appoint (AX 03- EC SOP 02/V 11) all the members.
- Members of the Ethics Committee shall be selected by the CE, GEF (M) on the recommendation and in consultation with the Member Secretary and Chairman of the Ethics Committee (if appointed).
- The appointment letter issued by the head of the institution to all members should enclose the Term of Reference (TORs) which include, at the minimum, the Role and responsibility of the member in the committee, Duration and Conditions of appointment.
- The EC is constituted in the following pattern:-

- Chairman- An eminent Non-institutional person from any background and shall be highly respected independent individual from outside the Institution.
- Member Secretary- A person who has knowledge in clinical research and ethics, have interest and good communication skills and has adequate time to this activity. The Member Secretary will be from the institution, committed to the task of coordinating and managing the activities of the committee.
- Other members from different Departments / Specialties / disciplines or areas etc. as per DCGI regulatory requirement with balanced representation of gender, with minimum mandatory requirement of below mentioned role:
  - ✓ Clinician: Majority of members from medical profession with qualification, experience and expertise in diverse health care specialties- who will review clinical aspect of the protocol like need for the study, outcome measures, inclusion exclusion criteria and the study design.
  - ✓ A lay person: A literate person from the community or public who is not qualified in medical or health science or not pursued a related career and will review patient centred viewpoint such as verification of safety /required study related details in consideration with informed consent form.
  - ✓ Legal expert: A person with basic degree in law who will review legal matter related to the study conduct such as insurance, clinical trial insurance, claim management, compensation and conflict resolution aspect.
  - ✓ Pharmacologist: A person with Scientific qualification and expertise (for drug trials pharmacologist) who will review scientific aspects in the protocol for instance drug interaction, identification of Adverse events/ SAE reported by the investigational product in the previous studies.
  - ✓ A social scientist: who will review social ethics aspect such as patient benefits, data confidentiality and advocacy to the patient rights.
- The licensing authority shall be informed in writing about the constitution of the Ethics Committee or in case of any change in the membership.

5.3. Criteria for selection of members:

- Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile and are expected to

be aware of local, social and cultural norms, as this is the most important social control mechanism.

- Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
- Competent in their field of expertise.
- The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields.
- New members will be identified according to the requirement i.e. as per the composition specified above and provided the potential member fulfills the conditions of appointment as defined below.
- The following qualities are sought in EC members:
  - Experience, education and expertise
  - interest and motivation
  - commitment and availability
  - respect for divergent opinions
  - integrity and diplomacy

5.4. Terms of Appointment:

5.4.a. Duration:

- The members of the EC will be appointed for duration of three years.
- At the end of the term of the members, the EC is reconstituted by incorporating new members in such a way that at least 40-50% of the existing members will remain in the Committee at any point of time to ensure the continuity in the functioning of the EC.
- The appointment procedure for membership will be followed so that it allows continuity, the development and maintenance of expertise within the EC and the regular input of fresh ideas and approaches.
- The retiring members are eligible for reappointment and membership can be continued. Extension of membership will be based on the recommendation of the Chairman & Member Secretary of EC.
- The Member Secretary, in consultation with the Chairman, shall intimate the Chief Executive, Gokula Education Foundation (Medical) about the Committee completing the tenure and the need to appoint new members. However the directives of the Chief Executive, Gokula Education Foundation (Medical) in the matter shall be followed.
- A Member Secretary, Chairman or member may be newly appointed before the completion of the tenure of the existing appointed Committee. This appointment will be effective for the remaining tenure of the existing Committee.

5.4.b. Renewal:

- The membership will be renewed after the stated term of three years
- The process of renewal will be as follows: Selection of Member Secretary and other members will be done in advance. Designated members of the EC should read, understand, accept and sign the

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS BANGALORE-560054 ETHICS COMMITTEE

agreement contained in the Confidentiality / Conflict of Interest form before the scientific and ethical review tasks of the EC commence (AX 04- EC SOP 02/V 11).

- If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of Appointment stated below.

5.4.c. Resignation / Replacement procedure:

- The members who have resigned may be replaced at the discretion of the appointing authority for the same.
- EC members who decide to resign must provide the Chief Executive, Gokula Education Foundation (Medical)/Chairman, EC the written notification of their proposed resignation date by stating the reasons at least 30 calendar days prior to the next scheduled meeting.
- In case of resignation, Chief Executive, Gokula Education Foundation (Medical) would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.
- The recommendations may be sought from the resigning member. Appointment may be made in consultation with Member Secretary and /or Chairman.
- A member can be replaced in the event of death or long term non availability or for any action not commensurate with the responsibility laid down in the guidelines deemed unfit for a member.

5.4.d. Termination / Disqualification procedure:

- A member may be relieved or terminated of his/her membership in case of:
  - Conduct unbecoming for a member of the Ethics Committee.
  - Inability to participate in the meetings on any grounds.
  - Relocation to another city or any such matter.
  - If a regular member fails to attend more than 3 consecutive meetings of EC without prior intimation, the membership shall be reviewed by the EC if the member is a regular absentee. If deemed necessary, the EC may decide to terminate the membership and recommend to the Chief Executive, Gokula Education Foundation (Medical), for necessary action.
- In all such situations/circumstances, Chief Executive, Gokula Education Foundation (Medical) will serve a letter of termination to the member.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted EC meeting and EC membership circular/roster will be revised.

5.5. Conditions of Appointment:

- Name, gender, qualification, and affiliation of EC members will be publicized in EC member list.
- Members must accept the appointment in writing (AX 02- EC SOP 02/V 11).
- Submit CV and training certificates in Ethics and /or GCP.
- The member must apprise themselves with below mentioned documents, the copy of which will be provided by the EC Secretary:
  - ICMR guidelines
  - ICH- GCP Guidelines

- Indian GCP Guidelines
- New Drugs and Clinical Trials Rules, 2019
- EC SOP

- Conflict of interest, if any, must be disclosed (AX 09- EC SOP 02/V 11).
- Members are required to sign the confidentiality agreement at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the EC in the course of its work.
- An investigator can be a member of the EC; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has presence as a PI, Co-I or potential conflict of interest.

5.6. Procedure to monitor and prevent conflict of interest:

- Conflict of interest is a situation in which personal and/or financial considerations have the potential to influence or compromise professional judgement in clinical service, research etc. The avoidance of conflicts of interest or the appearance thereof is important to ensure both the quality and credibility of research ethics review.
- Committee Members Financial Conflicts: Significant Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g. stocks, stock options or other ownership interests); intellectual property right (e.g., patents, copyrights and royalties from such right) , and board or executive relationships.
- Committee Members Role Conflicts: A Committee member who is also a part but not limited to either as an investigator or co- investigator for a proposal under review or is connected closely to a proposal (such as being on the same team as the principal investigator submitting the proposal or being in a supervisory position with the investigators) would have a conflict of interest if he or she participated in the ethics review of the proposal.
- Resolution of conflict: It has been recognized that the potential for conflict of interest will always exist but has faith in the EC and its Chairman to manage the conflict issues so that the ultimate outcome is the protection of human participants. The Committee shall ensure that its resolution of any situation involving a potential conflict of interest avoids not only the occurrence of unacceptable interests but also the appearance of such conflicts of interest. The Committee will therefore take below mentioned necessary steps to avoid any conflicts of interest.

- It is essential that members honour their responsibility as paramount and that they serve professionally as participants in research and scholarly activities. Self-discipline is the key to resolve this issue.
- The members of the Committee have an obligation to avoid unacceptable ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not conflict with their obligations to the institution or its welfare.
- It is important that all people participating in the submission and review of proposals involving human research avoid situations that could affect their ability to provide objective guidance for, or review of, research proposals regarding particular drugs, devices, vaccines, or other interventions.

- In the event of conflict of any committee members, the same will be declared prior to the review and such member shall voluntarily desist from partaking in any activity related with the said trial/protocol be decision making and/or monitoring of the participants, trial/protocol, until its conclusion.
- Similarly, the Chairman or Member Secretary will hand over his or her responsibility to the Acting Chairman/ Member Secretary whenever he or she has a role conflict. In case of Conflict of Interest for Member Secretary he/she will voluntarily withdraw him/her from discussion and decision and the decision will be communicated by the Acting Member Secretary.
- The conflict of interest shall be announced during the meeting prior to review and the minutes of the meeting shall record the declared conflict of interest and the steps taken to deal with the situation with regard to the Committee's deliberations and decisions.
- In all cases in which a conflict of interest is revealed, but is not so material as to warrant not approving the project, the Committee shall determine the type of description of such interest that needs to be included in the information provided to prospective participants in the research and shall ensure that the consent documentation also includes an appropriate disclosure.

• If an applicant submitting a protocol believes that an EC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairman. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict. If all pertinent information, determines that the faculty member's situation presents a serious conflict of interest, that conflict must be resolved. Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

6. Independent Consultants (IC):

• The EC may call upon, Independent Consultants/ subject experts who may provide special expertise to the EC on proposed research protocols, when the Chairman / Member secretary or the protocol reviewer or one of the EC members determine that a study will involve procedures or information that is not within the area of expertise of the EC members.

• These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies (e.g. genetic disorders, stem cell research etc.), or they may be representatives of communities, patients, or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities.

• Similarly, based on the requirement of research area, for example HIV, genetic disorders, pregnant or nursing women, children, vulnerable group, etc. specific patient groups/ subject experts may also be represented in the Committee to give opinion.

6.1. Consulting an IC during EC review process:

• Member Secretary in consultation with Chairman and EC members will nominate the name of IC(s) depending on the need either from different specialties of Medicine or subject experts or

patient representative. Care will be taken to avoid any potential Conflict of interest while selecting IC.

- Member Secretary on behalf of the EC will invite IC(s) to assist in the review of the research study and provide his/ her independent opinion in person by attending meeting or in writing. This may be done after seeking concurrence and confirming availability of the Independent Consultant through telephonic/ electronic communication.
- When invited for consultation, Member Secretary will request the consultant/expert to follow the provided EC SOP and sign a letter stating that they understand the confidentiality and conflict of interest agreement (AX 06- EC SOP 02/V 11) regarding meeting, deliberations, and related matters.
- The Secretary, EC may request a copy of the updated curriculum vitae of the Independent Consultant for EC records and future reference.

6.2. Review of research study proposal:

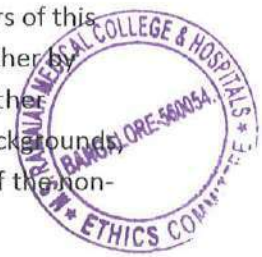
- The Secretary, EC will provide study protocol documents along with the Study Assessment Form (AX 07- EC SOP 02/V 11) to IC(s).
- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretary within a stipulated period or by a stipulated date. The assessment report provided by the IC(s) becomes a permanent part of the EC study file and will be reviewed by Member Secretary in the EC meeting when the concerned study is being discussed.
- If deemed necessary, the Chairman or Member-secretary may seek additional information or clarifications from the IC in writing or may invite the IC(s) to attend an EC meeting for providing additional information or clarifications that may be sought by EC members or Chairman. However, the IC will not participate in the decision making or voting process of EC decision on the research study.
- The opinion of the independent consultant or subject expert will also be captured in the Minutes of the meeting.
- If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet or any other incidental expenses, etc.

7. Office Bearers

The EC will have the following office bearers who have the expertise and professional qualifications to manage the proper functioning of the committee.

7.1. Chairman

The EC Chairman should be a highly respected individual from outside the institute, fully capable of managing the EC and the matters brought before it, with fairness and impartiality. The task of making the EC a respected part of the institutional community will fall primarily on the shoulders of this individual. The EC must be perceived to be fair and impartial, immune from pressure either by institution administration, the investigators whose protocols are brought before it, or other professional and non-professional sources. The EC Chairman will respect the diverse backgrounds, perspectives, and sources of expertise of all EC members, especially the contributions of the non-



scientists, and must have the ability to foster such respect among the EC members. Chairman will be responsible for:

- Conduct EC meetings and accountable for independent functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical) in all discussions and deliberations.
- Review disclosures to determine whether a conflict of interest exists and to determine appropriate management of the conflict of interest.
- Handling of complaints against Investigators, EC members, conflict of interest issues and requests for use of EC data etc.
- Ratify minutes of the previous meetings.
- Review SAE reports with causality assessment.
- If for reasons beyond control, the Chairman is not available a member of the EC who is not affiliated to the institute will be appointed as the Acting Chairman by the Chairman/EC members and he/she will chair the meeting.

7.2. Member Secretary

The Member Secretary will be from the institution, committed to the task of coordinating and managing the activities of the committee. He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.

If for any reasons, the Member Secretary is not available a member of the EC who is affiliated to the institute will be appointed as the Acting Member Secretary by the Member Secretary and will be informed to the Chairman, however the decision of the committee to the researchers will be communicated by the Member Secretary.

Member Secretary is responsible for:

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.
- Schedule EC meetings, prepare the agenda and minutes.
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Organize EC documentation, communication and archival.
- Communicate the EC decision to the researcher in writing.
- Sign documents and communications related to EC functioning.
- Arrange for training of EC members and EC secretariat.
- Ensure SOPs are updated as and when required.
- Delegate various responsibilities to appropriate and authorized individuals.
- Ensure adherence of EC functioning as per SOPs.
- Prepare for and respond to audits and inspections.
- Assess the need for expedited review/exemption from review or full review.
- Assess the need to invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

7.3. EC Secretariat:

- The EC secretariat will consist of the EC Chairman, Member Secretary, Secretary and office Assistants to help the Member Secretary to function efficiently and smoothly.
- The Secretary, EC will be appointed by the Chief Executive (CE), Gokula Education Foundation (Medical) and will effectively perform the following duties with due care and confidentiality:
  - ✓ Should read, understand, accept and sign the agreement contained in the form before the tasks of the EC commence (AX 05- EC SOP 02/V 11)
  - ✓ Assisting the Member Secretary to execute the duties efficiently including preparation of agenda and minutes of the meetings.
  - ✓ Receiving all research proposals and related documents and informing the Member Secretary and the assigned primary reviewer.
  - ✓ Organizing an effective and efficient tracking procedure for each proposal received.
  - ✓ Preparation, maintenance and distribution of study documents.
  - ✓ Coordinating and organizing EC meetings regularly.
  - ✓ Inviting independent consultant from relevant therapeutic areas to the scheduled meetings, if needed.
  - ✓ Writing/revising and implementation of EC SOP, as per the need and regulatory requirements.
  - ✓ Communicating with the EC members, Principal Investigators and the research coordinators, various administrative staff and running the office efficiently.
  - ✓ Ensuring adherence of EC functioning as per SOP's.
  - ✓ To raise invoice for EC fees and keep a track of all EC committee related financials.
  - ✓ Ensures that EC account has sufficient funds to carry out the day to day activities and other Committee functioning related expenditure.
  - ✓ Maintaining EC documentation and archiving them.
  - ✓ Arrangement of training for personnel and EC members.
  - ✓ Preparation for accreditation, audits.
  - ✓ Performing any other functions as instructed by Member Secretary/ Chairman.
- There will be an attendant/s /helper/s from the college who will help the Committee/ Secretary, EC in executing and arranging for the EC meetings. The attendant/s /helper/s will assist the Secretory, EC in
  - ✓ Arranging the EC meetings.
  - ✓ Dispatching sets of study documents to EC members and external experts.
  - ✓ Receiving the study related documents from investigators and dispatching the EC letters to the investigators.
  - ✓ Filing study related documents.
  - ✓ Archiving and maintaining the study files.
- The EC staff will report to the Member Secretary or Chairman.

8. Role and Responsibilities of EC members:

- The member's primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research participants.

- The Board shall independently examine, scrutinize and ensure that all the research proposals involving patients/human participants that are proposed to be carried out in M.S. Ramaiah Medical College and Hospitals (which includes both M.S. Ramaiah Teaching Hospital & M.S. Ramaiah Memorial Hospital) and any other outside hospital or institution are:
  - Sound in scientific design, have statistical validity and are conducted according to the parameters of GCP as well as local regulatory requirements.
  - Does not compromise the safety, rights and well-being of research participants.
  - The goal of research, however important, should never be permitted to override the health and well-being of the research participants.
  - Conducted under the supervision of medical persons with the required expertise.
  - Include solely, patients or healthy volunteers who have given voluntary informed consent.
  - Provisions for appropriate compensations wherever required.
- EC will take care that all cardinal principles of research ethics viz. Autonomy, beneficence, Non-maleficence and justice are taken care in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden, benefit and provision for appropriate compensation wherever required.
- Review and attend EC Meetings and participate in discussions and deliberations.
- Review periodic study status report, Continuing Annual Review reports and final study completion report.
- Carry out monitoring visit at site as and when required.
- Review Serious Adverse Event reports and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the EC meetings.
- Declare conflict of interest, if any at each meeting which should be recorded in the minutes. Such disclosure shall be sufficiently detailed and timely to allow the EC Member Secretary to transfer the project to another EC member.
- Carry out work delegated by the Chairman and/or Member Secretary.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the EC secretariat.
- The EC will maintain a list of projects submitted, approved / disapproved and the final outcome of each project.

8.1. Specific Role and Responsibilities of Basic Medical Scientist:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

8.2. Specific Role and Responsibilities of Clinician(s):

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics.

- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

8.3. Specific Role and Responsibilities of Legal expert/s:

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations, if any.

8.4. Specific Role and Responsibilities of Social scientist/ philosopher/ethicist/theologian:

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any.
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

8.5. Specific Role and Responsibilities of Lay person(s):

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

9. Quorum Requirement:

- A minimum of five members is required to form the quorum without which a decision regarding the project should not be taken. The quorum requirements of EC should have the following representation:
  a) Basic medical scientist
  b) Clinician
  c) Legal expert
  d) Social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
  e) Lay person from the community
- No quorum should consist members of one profession only or of one gender.

- The quorum should be maintained throughout the meeting and the names of members present during each meeting should be recorded to ensure compliance with New Drugs and Clinical Trials Rules, 2019.

10. Updating and Training of EC members:

- EC members have a need for initial and continued education regarding the science and ethics of biomedical research. All EC members must be conversant with ICMR Guidelines for Research involving Human Subjects, New Drugs and Clinical Trials Rules, 2019, ICH-GCP and Indian GCP Guidelines.
- All EC members will receive introductory training material in EC SOPs and research bioethics for reference and use and will be exposed to ongoing opportunities for enhancing their capacity for ethical review. All trainings will be documented.
- Training will be imparted on "Code of Ethics" by Clinical Research unit/ Member Secretary/ Chairman/ one of the senior EC member to all newly appointed members which will include orientation on ICH GCP, Indian GCP, ICMR, New Drugs and Clinical Trials Rules, 2019, EC SOP and other regulatory guidelines.
- The schedule for this "Code of Ethics" training will generally be as given below and the same will be documented:
  - Duration of Training: Half day
  - Frequency: At time of induction and whenever required.
  - Faculty: In house as well as outside experts may give the training
  - Record of such training will be maintained in EC office which will include CV of Trainer, Agenda as well as self-attested copy of certificate of participants.
  - Assessment of training: Will be done using pre and post-test.
- To provide continuing training to the members at regular intervals a yearly training matrix will be formed which will include a training schedule, topic to be covered and training calendar, and the same will be maintained in the Training records file.
- All relevant new guidelines, updated rules and regulations laid down by the Central Drugs Standard Control Organization (CDSCO)/DCGI will be brought to the attention of the members and discussions may be encouraged.
- Members will be encouraged and will be offered ongoing opportunities to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Members of the EC are required to complete periodic ethics training at least once every year.
- The EC members if have attained training in bioethics will summarize the new developments in the area of bioethics and regulations to the EC members prior to or at the end of the next convened EC meeting.
- The EC may conduct workshops on ethics in clinical research and good clinical research from time to time to impart training to the EC members.
- The EC may sponsor or reimburse the expenses of an EC member or prospective members for attending conferences, continuing education session workshop and/or training program etc. with the approval of the Chairman/ Member Secretary and/or the CE.

- Record of all such training will be maintained in EC member training record file.
- An individual selected as a new member of EC may be requested to attend a meeting as an 'observer' before being inducted as a member of the EC. All observers invited to any EC meeting must commit to maintain confidentiality regarding the EC work for each meeting that they are invited to attend by signing the confidentiality Agreement (AX 08- EC SOP 02/V 11).

11. Periodic self- assessments of EC:

- To ensure that the Committee is functioning efficiently, in compliance with all regulatory requirements and all the procedures, policies and SOP's are in place as per updated applicable regulations, a self-assessment of the EC will be performed using the Self-assessment tool for EC (AX 10- EC SOP 02/V 11) at least annually or if necessary, whenever an amendment is made in the SOP, or functioning of the Ethics Committee.
- The EC self- assessment will be done by a delegated EC member nominated by the EC Chairman/ Member Secretary or by all the committee member in the convened meeting.
- If the total score is more than 80%, the Committee is considered as compliant with the regulatory requirements however if the score is less than 80% then based on the assessment, a corrective and preventive action plan (AX 11- EC SOP 02/V 11) will be created by the Self-assessor and will be discussed in the EC meeting. If the Chairman and members agrees, the suggested plan will be implemented.
- Self-assessment tool may be amended on regular basis by the Secretary, EC to be in line with updated regulatory requirements.
- The EC members' performance will be evaluated once a year using a self-assessment form (AX 12- EC SOP 02/V 11) by each member.
- The EC assessment related documents will be placed in the EC Self-assessment files.

References

- http://www.nabh.co/ClinicalTrial.aspx- Self-assessment tool.

AX 01- EC SOP 02/V 11

Format for Invitation

From
The Principal and Dean
M S Ramaiah Medical College and Hospitals
Bangalore

To

_____
_____
_____

Sub: Constitution of Institute Ethics Committee.

Dear Sir/ Madam

I am pleased to inform you that you have been selected for the post of Chairman / Member Secretary / Member of EC (or have been selected to continue to be a member of the committee). Kindly send your written acceptance in enclosed format along with recent signed CV and training documents on Ethics and GCP. On recipient of your acceptance, I shall send you the formal appointment letter.

Yours sincerely

Signature

Principal and Dean
M S Ramaiah Medical College and Hospitals
Bangalore

AX 02- EC SOP 02/V 11

Acceptance letter by members of EC

From

_____

_____

To
The Principal and Dean
M S Ramaiah Medical College and Hospitals
Bangalore

Sub: Acceptance to be a member of Ethics Committee.
Reg. Ref: You're Letter dated:

Dear Sir/Madam,
In response to your letter stated above, I give my acceptance to become a Chairman / Member Secretary / Member of EC of M S Ramaiah Medical College and Hospitals, Bangalore or convey my acceptance for continuing to be the member of EC of M S Ramaiah Medical College and Hospitals, Bangalore. I shall regularly participate in the EC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.

As requested please find a copy of my signed and dated CV along with relevant training documents

Thanking you

Yours Sincerely
Signature
Date
Name of the member
Department & designation

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

AX 03- EC SOP 02/V 11

Appointment Order

Dr/ Mr. / Mrs.: Date:

I am pleased to appoint you as_____ of the Ethics Committee (EC) at M S Ramaiah Medical College and Hospitals w.e.f. _____ for a term of 3year provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. Conflict of interest, if any, must be disclosed.
3. You consent to sign confidentiality and conflict of interest agreement between you & the EC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. The Term of reference has been enclosed for your reference however other Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of Ethics Committee (EC) at M S Ramaiah Medical College and Hospitals (Enclosed).
You will be paid an Honorarium for your services rendered & as per the guidelines given in EC, SOP.
We sincerely hope your association with Ethics Committee (EC) at M S Ramaiah Medical College and Hospitals will be fruitful to the Institute & the Community we serve.

Signature of Principal and Dean
M S Ramaiah Medical College and Hospitals
Bangalore

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

AX 04- EC SOP 02/V 11

Confidentiality and Conflict of Interest Agreement form for EC Members

In recognition of the fact, that I, ... (Name of EC Member) herein referred to as the "Undersigned", has been appointed as a member of the Ethics Committee (EC), would be asked to assess research studies involving human participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Confidentiality Agreement

I, the Undersigned, accept that the confidential information contained in the review material submitted by the applicant of the clinical research proposal to the EC, shall be maintained in confidence with the same degree of care the EC hold its own confidential information and shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Confidential Information provided for review shall be returned to EC Secretary after discussion and final review. However, I understand that EC records may be subjected to review by relevant regulatory authority.

Conflict of Interest

In accordance of the policy of the EC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the EC. The Undersigned will immediately disclose to the Chairman of the EC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

Agreement on Confidentiality and Conflict of Interest

I, ... (Name of EC Member) have read and I accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Signature of Chairman of the EC Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

Signature Date

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

AX 05- EC SOP 02/V 11

Confidentiality Agreement Form for Secretary, EC

I, _____(name and designation) herein referred to as the "undersigned", have been appointed as a Secretary of the EC office. This agreement encompasses any information deemed confidential provided to the Undersigned in conjunction with the duties as a Secretary of the EC. All confidential information (and any copies and notes thereof) shall remain the sole property of the EC. The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him or her during his tenure of service.

I, _____ (name of the EC, Secretary) have read and I accept the conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Signature of Chairman of the EC Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

Signature Date

AX 06- EC SOP 02/V 11

Confidentiality and Conflict of Interest Agreement Form for Independent Consultants

I, _____ (Name) as a non-member of EC understand that the copy (ies) given to me by the EC is (are) confidential. I shall use the information only for the indicated purpose as described to the EC and shall not duplicate, give or distribute these documents to any person(s) without permission from the EC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

I understand that it is the policy of the EC that no reviewer may participate in the review, comment or approve of nay activity in which he/she has a conflict of interest except to provide information as requested by the EC. I hereby declare that I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the EC to me.

_____ _____

Consultant Signature Date

_____ _____

Signature of Chairman of the EC Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

Consultant Signature Date

AX 07- EC SOP 02/V 11

Study Assessment Form for an Independent Consultant

Protocol Title and No:	
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?	☐Yes ☐No
Comments on the protocol:	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	
Remarks:	☐Recommend ☐Recommend after incorporation of changes suggested ☐Not Recommend
Name of the Consultant reviewing the project:	
Signature with Date:	

AX 08- EC SOP 02/V 11

Confidentiality Agreement Form for Observer

I, _____ (Name and Designation) understand that I am being allowed to attend the EC meeting on _____ at _____ as an Observer. The venue of the EC meeting will be _____. I may become aware of some confidential information during the course of the EC meeting.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

_____ _____

Signature Date

_____ _____

Signature of Chairman of the EC Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

Signature Date

AX 09- EC SOP 02/V 11

Conflict of Interest Declaration for EC Members

I, ... (Name of EC Member) is aware of the policy of the EC regarding conflict of interest and that no member may participate in the review, comment or participate in decision making of any activity in which he/she has actual/ potential conflict of interest except to provide information as requested by the EC.

I declare _____ (actual or potential COI) in relation to the proposal entitled "_____" submitted for review to the EC. The reason for COI is_____.

I will refrain from the review process and /or discussion at the EC meeting and also will not take part in ongoing and periodic review and monitoring of this study.

_____ _____

Signature Date

_____ _____

Signature of Chairman of EC Date

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

AX 10- EC SOP 02/V 11

Self-Assessment Tool for EC

Sl. No.	Elements	Documentation (Yes/No)	Implementation (Yes/No)	Scores (0/5/10)
1.	**Authority for formation of Ethics Committee: There shall be documented Procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations.**			
1.1	Procedures shall be followed to specify the authority under which the Ethics Committee is established and administratively governed.			
1.2	There shall be a documented policy to ensure the independence of the Ethics Committee in its functioning and decision making.			
1.3	Ethics Committee shall function as per applicable rules and regulations.			
2.	**Standard operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.**			
2.1	Procedures shall be in place and well defined for the development, review and revision of SOPs.			
2.2	List of mandatory procedures for Ethics Committee are as follows: i)Terms of reference for Ethics Committees. ii) Protocol Submission iii) Ethical Review iv) Decision making, minutes recording, post meeting activities including monitoring. v) Documentation and archiving			
3.	**Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.**			
3.1	Composition shall be multidisciplinary and multisectorial and adequate for its functioning.			
3.2	Subject experts and representatives of vulnerable subjects shall be invited as required with prior intimation.			
3.3	Membership, appointment, reconstitution and resignation shall be denied as per terms of reference.			
3.4	Roles and responsibilities of members shall be well denied.			
3.5	Ethics Committee members shall be trained (initial and ongoing) in applicable rules and regulations and Ethics Committee SOPs.			
3.6	Conflict of interest and confidentiality shall be addressed at the time of composition.			
4.	**Protection of subject rights, safety and wellbeing: The Ethics Committee follows documented procedures for subject protection.**			

4.1	Rights and responsibilities of subject shall be documented and are specified.			
4.2	Subject's participation and withdrawal from the trial shall be voluntary and with prior intimation.			
4.3	Subjects shall be informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial.			
4.4	Confidentiality and privacy of subjects shall be protected.			
4.5	Monitoring of trials shall be done to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.			
4.6	Compensation provided to subjects for participation in the trial shall be appropriate and as per the rules and regulation and is reflected in the contract.			
4.7	Serious adverse events shall be addressed, adequate medical care provided and an Appropriate reporting mechanism is followed as per applicable rules and regulations.			
4.8	Compensation for injury to the subject shall be as per the rules and regulations and monitored for noncompliance.			
4.9	Complaints and concerns of subjects shall be addressed and managed appropriately, if the need arises.			
5.	**Administrative support: The Ethics Committee follows documented procedures / terms of reference (TOR) to ensure that administrative support for its activities is adequate.**			
5.1	Adequate finance, human resource allocation and secretariat for administrative work and record keeping shall be ensured, with due care and confidentiality.			
5.2	There shall be financial transparency of Ethics Committee activities and functioning.			
5.3	There shall be a procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory authority.			
6.	**Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and Periodic review.**			
6.1	Review shall be done by the Ethics Committee in a formal meeting within a reasonable time following appropriate submission of documents by investigator as per rules and regulations and Ethics committee requirement.			
6.2	Initial review of proposed clinical trial shall evaluate the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations.			
6.3	Informed consent document, assent form (as applicable) and translations shall be reviewed for			

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

	appropriateness of language, accuracy and completeness of information.			
6.4	Ethics Committee shall review the informed consent processes proposed to be followed at the site for a particular trial to ensure that subject/LAR/ impartial witness are provided appropriate information, adequate time is given and impartial witness used as applicable.			
6.5	Recruitment strategies shall be evaluated.			
6.6	Proposals involving special group and vulnerable population shall be evaluated as per rules and regulations.			
6.7	Contract and budget shall be evaluated, for indemnity, compensation, roles and responsibilities as per applicable rules and regulations.			
6.8	Review of amendments to the originally approved protocol, consent forms and investigators brochure shall be done in formal meetings to evaluate the risk to trial subjects.			
6.9	Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.			
7.	**Decision making and post meeting activities: The Ethics Committee follows Documented procedures for decision making process and post meeting activities.**			
7.1	Decision making process (approval/ disapproval/ pending/ revoking) shall be as per applicable rules and regulations, ensuring quorum and consensus/voting requirements are fulfilled.			
7.2	The subject shall be recruited into the trial only after written approval from Ethics Committee and approval by regulatory authority.			
7.3	Conflict of interest shall be declared prior to the review and voluntary withdrawal during Decision making process is documented.			
7.4	Decisions shall be based on risk assessment, scientific validity and adherence to ethical Principles for the initial and periodic approvals.			
7.5	Deliberations and decisions made during the meetings shall be documented, approved, signed and maintained as minutes of meeting.			
7.6	Protocol deviations and non-compliances shall be evaluated and appropriate actions shall be taken as per rules & regulations.			
7.7	Serious adverse events shall be analyzed and compensation amount assessed and reported to regulatory authority as per rules and regulations.			
7.8	All decisions/opinions shall be notified to the investigator in writing.			

8.	**Monitoring: The Ethics Committee follows documented procedures for Monitoring and for-cause assessment.**			
8.1	Subject's rights, safety and wellbeing shall be monitored.			
8.2	Adequacy and continuity of consent process shall be ensured.			
8.3	For-cause assessments shall be conducted following non-compliance and/or complaints for the trials approved by the ethics committee.			
8.4	Opportunities for improvement shall be identified and appropriate actions initiated.			
9.	**Self-assessment: The Ethics Committee has and follows documented procedures for self-assessment.**			
9.1	Periodic self-assessments shall be conducted.			
9.2	Corrective and preventive actions (as required) shall be implemented accordingly.			
10.	**Record keeping and archival: The Ethics Committee follows documented Procedures for record keeping and archiving.**			
10.1	Security, confidentiality and integrity of all proposals and associated documents shall be reviewed from time to time and administrative communication shall be maintained as per regulatory requirement and with confidentiality.			
10.2	Documents and records shall be archived after completion /termination of trial as per applicable rules and regulations.			
10.3	Record retrieval policies and procedures shall be in place to ensure access to information for inspection and audit and continual protection of trial subjects, post-trial closure with prior permission in writing.			
	Total Score			

Name of the Member performing the activity/ Member Secretary name (In case assessment done by committee): _____

Signature of the Member/Member Secretary performing the activity: _____

Date: _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

AX 11- EC SOP 02/V 11

Corrective and Preventive Action Plan

Opportunity for improvement	Goal	Action plan, Person(s) Responsible, and Timeline
(a)	(a)	(a)
(b)	(b)	(b)
(c)	(c)	(c)

Name of the Member performing the activity/ Member Secretary name (In case assessment done by committee): _____

Signature of the Member/Member Secretary performing the activity: _____

Date: _____

AX 12- EC SOP 02/V 11

Self-Assessment Form for Ethics Committee Members

1. Role in the committee:
2. Current tenure:
3. Terms served:
4. Training received:
5. Type of training received:
6. No. of meetings held in current year:
7. No of meetings attended:
8. Reviewed projects as primary reviewer: Yes/No
9. Participation in SAE report review process- Yes/No
10. Participation in site monitoring visits - Yes/No
11. Number and type of continuing training workshops organised for EC members (applicable to Member Secretary):
12. Number and type of continuing training workshops organised for staff of the EC secretariat (applicable to Member Secretary):
13. Whether quorum requirement fulfilment ensured as per New Drugs and Clinical Trials Rules, 2019in EC meetings (applicable to Chairman): Yes/No
14. Whether considerations related to conflict of interest considered (applicable to Chairman): Yes/No
15. Any significant contribution to the field of research ethics:

Using a 5-point scale where 5 means excellent and 1 means very poor (5=Excellent 4=Good 3=Fair 2=Poor 1=Very Poor), please rate your performance on the EC by writing appropriate number for following each question. Following this, please note any areas for improvement and outline a plan for improvement. This form is for your personal development as a member of the EC.

a. My attendance at the EC meetings was:
b. My participation at the EC meetings was:
c. My preparation for the EC meetings in terms of reading materials, performing tasks, and so on was:
d. My involvement with the EC's tasks and functions was:
e. I would rate my overall performance on the EC as :

I can improve in the following areas:

My plan for improvement is as follows:

Any other comments _____

Name of the Member:

Signature of the Member:

Date:

Remarks by Chairman/Member Secretary (NA for Chairman):

Name of the Chairman/ Member Secretary:

Signature of the Chairman/ Member Secretary:

Date:

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Application Procedure

SOP Number	EC SOP 03/V 11
Effective Date	28 May 2019
No of pages	01 to 10
Superseded Version Number & Date	V 10 Amendment 1 & 29 Dec2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/2019

Table of Contents:

1. Purpose

This SOP is designed to describe and act as a guideline for the EC Secretariat to manage research study submissions.

2. Scope

The scope of this SOP includes the following -

- Submission for initial review
- Resubmission of study with modifications
- Amendment of Protocol and any other amendments
- Study Report for Periodic review/Continuous review
- Study completion/termination
- Any other documents

3. Responsibility

It is the responsibility of the EC Member Secretary/Secretary to receive record and distribute the study documents for EC review.

4. Detailed Procedure

4.1 Receive Submitted package

- For the review of study, investigators should submit all study related documents to the EC, at least three weeks in advance to the next scheduled meeting. The PI should submit research proposal to the EC for review and approval under any of the 5 sections mentioned below:
  - Initial Review Application
  - Resubmission of Study with Corrections
  - Amendment of Protocol or any other amendments
  - Periodic (every six months from date of approval)/Continuous review study Reports
  - Study Completion / Termination

4.2. Verification, distribution and storage of Submission

- On the receipt of the study related documents, Secretary, EC/ Member Secretary will check the submissions to ensure that all mandatory documents are enclosed.
- Check completeness of necessary information with signature of authorized person in the submission letter.
- Notify the investigators/ representative, if the submission is incomplete with details of missing documents.
- The Secretary, EC /Member Secretary will stamp, sign & date the first page of the cover letter (one original and one copy) confirming receipt of the documents. The signed Xerox will be returned to the applicant for their records.
- For the initial submission, Member Secretary will assign a reviewer for each new protocol.

- After the last day of submission is over, for clinical trials all the study related documents (hard or soft/electronic copy) and the Application form along with applicable Reviewer Template will be sent to the assigned Reviewer ensuring sufficient time for review. The remaining set of documents will be distributed to all other members along with applicable Reviewer Template.
- For clinical trials one hard copies will be stored under controlled access storage in EC office, in the appropriately labelled (in serial order) respective study EC submission file.
- For clinical trials a list of the protocol number with EC file number and assigned reviewer name will be maintained in the EC office for easy access.
- For Academic trials, after the last day of submission is over, the protocol and related documents will be distributed to all the EC members and one hard copy of all the proposals discussed in a particular meeting will be stored meeting wise in common EC file.

4.3 Detailed description of Initial Review Application

- For Initial review the applicant of the Clinical Trial proposal is required to submit the application letter along with the Application Form for Initial Review of Clinical Trials (AX 01-EC SOP 03/V 11) duly signed by the Principal Investigator (PI) or Co-investigators (Co-I) and the required no of soft/electronic format or hard copies (i.e. if hard copies then the no. of copies should be equivalent to the no. of EC members, if soft copies then it should be submitted along with two sets of hard copies) of the following documents at least three weeks in advance to the EC meeting:
  1. Submission letter to Member Secretary/Chairman along with name of the applicant with designation and name of the institute/hospital/field area where the research will be conducted
  2. Application form for initial review (AX 01- EC SOP 03/V 11).
  3. Protocol of the Research study/project.
  4. Investigator's Brochure and any safety information available.
  5. Package insert/product insert (if applicable).
  6. Informed Consent Form and Subject Information Sheet in English and the relevant translated languages and their back translations (if available) along with Child Assent Forms (if applicable) and Audio video informed consent (if applicable).
  7. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for this purpose.
  8. Regulatory clearance from appropriate regulatory authorities i.e. DCGI approval/ ICMR /Health Ministry Screening Committee (HMSC) (if applicable).
  9. Any other project specific documents like proforma, case report forms, guidelines, questionnaires, follow – up cards, etc.
  10. Current signed CV of the Principal Investigator.
  11. Investigator's undertaking.
  12. Any regulatory clearances required, as applicable.
  13. Documentation of clinical trial registration in Clinical Trial Registry (if available at the time of initial submission)

14. The draft/final Investigator's agreement with the sponsor (Tripartite Clinical Trial Agreement to be made while commencing a project involving Sponsor or representative, Principal Investigator, the Institution as signatories).
15. Insurance/Indemnity policies, indicating who are covered and compensation for participation and for serious adverse events occurring during the study participation.
16. Any other information relevant to the study.

- The applicant of the academic or student proposal is required to submit through proper channel the application letter with below mentioned details and required no of soft/hard copies (i.e. if hard copies then the no. of copies should be equivalent to the no. of EC members, if soft copies then it should be submitted along with two sets of hard copies) of the following documents duly signed by the Principal Investigator (PI) or Co-investigators and the Head of the Department, which should be forwarded to the EC at least three weeks in advance prior to the EC meeting:
  1. Name of the applicant with designation.
  2. Name of the institute/hospital/field area where the research will be conducted.
  3. Protocol of the Research study/project/ amendment to the protocol.
  4. Informed Consent Form and Subject Information Sheet in English and the regional languages, if required.
  5. Any other project specific documents like proforma, case report forms, guidelines, questionnaires, follow – up cards, etc.
  6. Source of funding.
  7. Any other information relevant to the study.
- The EC would have to be notified of any proposed payments to be made to study patients towards compensation and reimbursement of incidental expenses.

4.4 Resubmission of study with corrections as per EC suggestions

- If revision is to be made, the PI will submit one copy of the revised document along with justification for amendment or modification, and clearly highlighted / demarcated sections which have undergone change within a stipulated period of time as specified in the communication or before the next meeting.
- The EC Secretary/ Member Secretary will verify the completeness and reconfirm that the copies contains the modification highlighted with respect to the earlier submission. The EC Secretary/ Member Secretary will perform the steps 4.2.

4.5 Application for amendment of Protocol or any other amendments

- For amendments in protocol, ICF or any other study related documents the applicant of the Clinical Trial proposal is required to submit the application letter with the details of the amended documents along with required no of soft/electronic format or hard copies of the documents (i.e. if hard copies then the no. of copies should be equivalent to the no. of EC members, if soft copies then it should be submitted along with two sets of hard copies) duly signed by the Principal Investigator (PI) or Co-investigators at least three weeks in advance prior to the EC meeting.

- The EC Secretary/ Member Secretary will verify the completeness of the submission as mentioned in section 4.2.
- The amended study documents should be approved by the EC prior to making any changes in study procedures.
- Amendment in Protocol, IB, ICF and other subject related documents should be submitted for approval, however administrative changes (as mentioned below) can be submitted for notification provided that the basic Protocol, IB, ICF's and other subject related documents are reviewed and approved by EC earlier. Changes which are considered to be of administrative nature in these documents are:
  - ✓ Change in EC/ sponsors name and contact details
  - ✓ Typographical errors
  - ✓ Grammatical corrections

4.6 Study Report for Periodic review/Continuous review of Approved Clinical Research studies

- The EC will receive a copy of study periodic report every six months from the date of approval in the prescribed format and related documents (as per EC SOP 07/V 11) for the approved Clinical trials.
- The EC Secretary will verify the completeness of the study report submission as mentioned in section 4.2 and will send to the Member Secretary along with the check list (as per EC SOP 07/V 11) for his/her review and the same will be added in the next convened full board meeting of EC.

4.7 Research study Completion/termination report

- The EC will receive a copy of Study Completion Report / termination in the prescribed format (as per EC SOP 07/V 11).
- The EC Secretary will verify the completeness of the study report submission as mentioned in section 4.2 and will send to the Member Secretary for his/her review and the same will be added in the next convened full board meeting of EC.

References

- EC SOP 07/V 11- Continuing Review of Study Protocols.
- EC SOP 04/V 11- Review Procedure

AX 01- EC SOP 03/V 11

Application Form for Initial Review of Clinical Trials

(Please type the details, Tick √ in the box for the appropriate answer, Tick/ Write NA if question is not applicable)

1	**Title of the protocol:**	
2	**Sponsor & CRO Name and Contact Address (If sponsor is not from India, contact address in India):**	
3	**Number of studies being handled as PI** (Information to be given: no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study):	
	In Screening:	
	In Follow up:	
	No. of Studies Pending for closeout:	
	Studies in pipeline (approved by EC):	
4	**Clinical Trial:** Introduction, phase I or II data on the drug, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures (can be submitted as enclosure).	
4.1	What does the study involve use of (Medicines/Vaccines/Device/Herbal Remedies or Indian system of medicine/others, specify/ NA)	
4.2	Is it an Investigational New Drug (IND)?	___Yes ___No
	Is it a New Chemical Entity (NCE)?	___Yes ___No
	Investigator's Brochure submitted?	___Yes ___No ___NA
	Preclinical Studies done?	___Yes ___No ___NA
	Clinical Study is in :	___ Phase I ___ Phase II___ Phase III ___ Phase IV ___NA
	In case test drug is already marketed in India to submit package insert:	___Yes ___No ___NA
4.3	Does it involve a change in use, dosage, route of Administration of an already marketed drug?	___Yes ___No ___NA
4.4.	Is the proposal being submitted for clearance from DCGI/ Health Ministry's Screening Committee (HMSC) /ICMR?	___Yes ___No ___NA
	If yes, date of permission :	

	If No, specify the reason?	
4.5	Is the trial registered with Clinical Trial Registry India-CTRI (mandatory for drug trials)/ any other WHO platform registry?	___Yes ___No
	If yes, Registration number: If not registered, state the reason	
4.6	Age Criteria:	
	Duration of study:	
	No. of visits:	
	Will research participants from both genders be recruited?	
	Type of research participants (Healthy Volunteers or Patients):	
	Explain reason for inclusion of Normal / Healthy Volunteer, Student, Staff of the institute in the study (if applicable).	
	Vulnerable research participants involved:	
	Names of participating Countries:	
	Expected no of study sites:	Globally:___ and from India:___
	Expected no. to be randomized (total target):	Globally:___ and from India:___
	Target for our site:	
	Proposed methods for patient accrual including advertisement(s) etc. proposed to be used:	
	In what way will you ensure the confidentiality and privacy of the participants (Study involves Direct Identifiers/ Indirect Identifiers or coded/ Completely anonymized or delinked)	
	Will any sample collected from the patients to be sent abroad?	___Yes ___No ___NA
	If yes, are the necessary approvals in place:	___Yes ___No (specify reason)
5	**Risks & Benefits:**	
	Is the risk reasonable compared to the anticipated benefits to research participants / community / country?	
	Describe all possible risks and discomfort for Participants due to use of intervention and/or data collection methods proposed. Describe expected degree and frequency of such risks, discomfort, side effects of	

	drug etc.	
	Is there a benefit to the research participants Direct/In Direct? Or Benefit to society	
	Is there a data & safety monitoring committee/ Board (DSMB)	
	Is there compensation/inducement for participation:	___Yes ___No ___NA
	If Yes, Monetary/In kind: Specify amount and type:	
	Is there a compensation for participants for out of pocket expense for trial:	___Yes ___No ___NA
	If Yes, Specify amount:	
	Is there provision for compensation for study related injury?	___Yes ___No ___NA
	If Yes, by Sponsor/ by Investigator/ by insurance company/ by any other:	
	What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and Biologics for the study participants/Participants, if it is found to be effective?	
6	**Consent (If written consent will not be obtained, give reasons):**	
	Consent form: (tick the included elements)	____Simple language ____Alternatives to participation ____ Statement that study involves research ____ Confidentiality of records ____ Contact information (PI and EC) ____ Purpose and procedures ____ Statement that consent is voluntary ____ Risks & Discomforts ____ Benefits ____ Right to withdraw ____ Compensation for study related injury ____ Compensation for cost of travelling for study related visits ____Benefits, if any, on future commercialization (if, applicable) ____Consent for future use of biological samples (if, applicable)

	Describe how, where, when and by whom the Informed Consent will be obtained.	
	Describe how much time the participant will be given to consider participation and decide.	
	Describe for Plan of Voluntary, Non-Coercive Recruitment of Participants	
	Describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, etc.(if applicable).	

Principal Investigator Signature

Date

RAJAJI MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Review Procedure

SOP Number	EC SOP 04/V 11
Effective Date	28 May 2019
No of pages	01 to 23
Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The EC should review, every research study involving human participants and other forms of studies and the study should be initiated only after EC approval is received. The EC should evaluate the scientific rationale, scope, methodology and the ethical aspects of the study. The purpose of this Standard Operating Procedure (SOP) is to describe how the EC members will review an initial submission of the research study for approval using the Reviewer Templates. The Reviewer Template are designed to standardize the review process and to facilitate reporting, recommendations and comments offered to each study.

2. Scope

This SOP applies to the review and assessment of all studies submitted for initial review and approval of the EC. Relevant comments made during discussion and deliberation about a study should be recorded in the minutes of the meeting. The decision reached by the EC will be communicated to the PI.

3. Responsibility

All members of the EC are responsible for implementing this SOP. The EC Secretariat is responsible for receiving, verifying, and managing the hard/soft copies of the received submission. In addition, the Secretary should create a study specific EC file, distribute the packages and study assessment forms to the assigned EC members for review. EC members are responsible for receiving, verifying, and reviewing the research protocols.

4. Definition

Minimal Risk: Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life (ICMR 2006).

5. Detailed procedure

- Each application will be screened by the Secretary, EC /Member Secretary for their completeness.
- All properly submitted applications will normally be reviewed during the month following the submission, according to the review procedure as described below.
- Each clinical trial protocol will be assigned to one of the Scientific Member of the committee by Member Secretary based on the area of expertise, who will be considered as assigned reviewer for the study and will be responsible for the initial protocol review of the study, which will be documented in the Assigned Reviewer for Clinical Trial (AX 07-EC SOP 04/V 11).
- Assigned reviewer will review the study documents and will give his/her comments on the study using the Reviewer Template for Clinical trial Study/ ICF/ Risk Benefit assessment (AX 01-EC SOP

04/V 11; AX 02-EC SOP 04/V 11; AX 04-EC SOP 04/V 11). Other members will give their comments using the relevant templates based on their role as mentioned below:

- Basic medical scientist- Reviewer Template for Risk Benefit Analysis (AX 04- EC SOP 04/V 11)
- Legal expert: Reviewer Template for Legal Aspect of Clinical Trial (AX 03- EC SOP 04/V 11)
- Social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person: Reviewer Template for Clinical Trial ICF (AX 02- EC SOP 04/V 11)
- Lay person from the community: Reviewer Template for Clinical Trial ICF (AX 02- EC SOP 04/V 11)

- After the meeting filled Reviewer Template will be placed in the respective study EC submission file along with initial submission letter.
- The requisite quorum of members (minimum 5) as per New Drugs and Clinical Trials Rules, 2019 will be present at each review meeting, with the Legal person, Social Scientist, a Clinician, a Basic Medical Scientist (preferably one pharmacologist) and a lay person to complete the mandatory quorum.
- All EC members are expected to declare competing conflicts of interest with respect to research proposals or investigators, if any, before commencement of each meeting in writing. EC members are expected to agree to not to be present during presentation of proposals in which they are investigator or co-investigators, unless requested to answer clarifications; they may present proposals if they are Principal Investigators, but in both situations should leave the room before EC discussions and decisions. It is the duty of EC members to adhere to this without being reminded of this duty.
- The Principal Investigator or a study team member may be called to the meeting to offer clarification or answer specific queries. For PG trainees and students, the guides or co-guides may be called to the meeting to offer clarification or answer specific queries.
- If required, Independent consultants/subject experts or community representative will be invited to offer their views.
- The names of the members who attended the meeting in which the project was reviewed will be mentioned in the response letter from the EC, along with a comment on non-participation of the study team member.

6. Element of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The committee members shall review the proposal with reference to the following:

6.1. Scientific design and conduct of the study

- The rationale and need for the study in view of existing literature.
- Scientific design and conduct of the study.
- The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the number of research participants.

- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- The justification for the use of placebo in control arms (if any), criteria for withdrawal of research participant or study termination.
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board (DSMB).
- Adequacy of investigators and supporting staff.
- Adequacy of facilities and infrastructure of study sites.
- Plans for data analysis and reporting.

6.2. Protection of rights, safety and wellbeing of Research Participants

- Competence of investigators, research and supporting staff by qualification and experience for the purpose of the study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- The medical care to be provided to research participants during and after the course of the research.
- Steps to be taken if research participants voluntarily withdraw during the course of the research.
- The arrangements, if appropriate, for informing the research participant's general practitioner or consultant, including procedures for seeking the participant's consent to do so.
- A description of any financial costs to research participants; the rewards and compensations for research participants (including money, services, and/or gifts);
- The provisions in the clinical trial agreement for compensation/treatment in the case of the injury/ disability/ death of a research participant attributable to participation in the research.
- The insurance, indemnity and compensation arrangements is done in the contract.
- Criteria for withdrawal of patients, suspending or terminating the study.
- The criteria for extended access to the emergency use of and/or compassionate use of study product.
- Availability of products after the study, if applicable.
- Adherence to all regulatory requirements and applicable guidelines.
- Procedures for determining when activities are exempt from applicable laws and regulations and when permitted by law or regulation.
- Charter of Rights of the Clinical Trial Participants will be displayed in the hospital.

6.3. Risk- Benefit analysis

- As per regulations two of the required criteria for granting EC approval of the research are:
  - ✓ Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- ✓ Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

- In evaluating risks and benefits, the EC will consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.
- The EC is responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result. It must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the risks. The EC cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits.
- Ways to Minimize Risk:
  - ✓ Assure that potential subjects will be provided with an accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.
  - ✓ Assemble a research team with sufficient expertise and experience to conduct the research.
  - ✓ Ensure that the projected sample size is sufficient to yield useful results.
  - ✓ Collect data from standard-of-care procedures to avoid unnecessary risk, particularly for invasive or risky procedures (e.g., spinal taps, cardiac catheterization).
  - ✓ Incorporate adequate safeguards into the research design such as an appropriate data safety monitoring plan, the presence of trained personnel who can respond to emergencies, and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords).
- Note that the participants may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. When this is reasonable then it cannot be termed as benefit. During the period of research if the participant requires treatment for complaints other than the one being studied, necessary free ancillary care or appropriate referrals may be provided. However, payments should not be so large or the medical services so extensive as to make prospective participants consent readily to enroll in research against their better judgment, which would then be treated as undue inducement. All payments, reimbursement and medical services to be provided to research participants should be approved by the EC.

6.4. Protection of Research Participant Confidentiality and Privacy

- The EC shall determine on a protocol-by-protocol basis whether there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data at each segment of the research from recruitment to maintenance of the data in order to approve human subject's research.
- If possible, data should be collected anonymously or the identifiers should be removed and destroyed as soon as possible and access to research data should be based on a "need to know" and "minimum necessary" standard.
- When it is necessary to collect and maintain identifiable data, the EC will ensure that the protocol includes

- ✓ A description of the persons who will have access to personal data of the research participants, including medical records and biological samples.
- ✓ The measure taken to ensure the confidentiality and security of personal information concerning research participants.

6.5. Informed Consent Document and Process

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, adequate time to be given to the potential study subject or their legally acceptable representative (LAR) and that the impartial witness is used when applicable.
- The adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s).
- Patient information sheet and informed consent form and assent form (when applicable) in local language and translation will be reviewed for appropriateness of language, accuracy and completeness of information. If a language is not known to any of the members then an external person may be invited to review the translation and confirm the appropriateness, with prior notice.
- Clear justification for the intention to include research participants who cannot consent, and a full account of arrangements made to obtain their consent/ authorization.
- Ensure adequate measure to protect prospective participants who cannot give consent or whose decision-making capacity is in question (vulnerable subjects) by checking the ICF format during the review, and a full account of arrangements made to obtain their consent /authorization.
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being.
- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
- ICF Requirements for clinical trials:
  - ✓ Site Specific Informed Consent Form along with translation in regional languages is mandatory.
  - ✓ Study involves research.
  - ✓ Participation is voluntary.
  - ✓ For all ICFs related to sponsored drug/ device trials following information is mandatory.
    - i. Date of Birth/ Age
    - ii. Qualification
    - iii. Occupation
    - iv. Annual income of the subject
    - v. Name and address of the nominee(s) and his/her relation to subject
  - ✓ In addition to the details about travel allowance, ICF should have well defined clause about the "compensation" in terms of when and who will be responsible for the same.
  - ✓ Contact details of EC should be available.
  - ✓ Participant can discontinue participation at any time without penalty or loss of benefits with prior intimation.

6.6. Informed consent in emergency protocols

- This section describes responsibilities related to informed consent when research participants are enrolled in emergent circumstances, as when human participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- If a legally authorized representative or family member is told about the research and the participant's condition improves, the participant is also to be informed as soon as feasible.
- Procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions will be made according to applicable laws, regulations, codes and guidance.

6.7 Waiver of written informed consent

- The following criteria as per ICMR 2006 guidelines must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent, provided that such studies have protection in place for both privacy and confidentiality and do not violate the rights of the participants .
  - ✓ The proposed research presents no more than minimal risk to subjects. E.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease.
  - ✓ When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective. E.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS / conducting phone interviews with homosexuals.
  - ✓ Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
  - ✓ Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc.
  - ✓ In emergency situations when no surrogate consents can be taken. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the EC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.
- A request to waive written informed consent must be accompanied by a detailed explanation from PI. The investigator is also required to provide assurance regarding protection of identity of research participants, maintenance of confidentiality about the data of the research participants and do not violate the rights of the participants.

6.8. Community Considerations

- Involvement of the community will be done, wherever necessary.
- The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
- The steps taken to consult with the concerned communities during the course of designing the research.
- The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health need.
- A description of the availability and affordability of any successful study product to the concerned communities following the research.
- The manner in which the results of the research will be made available to the research participant and the concerned community.

6.9. Recruitment of Research Participants

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity).
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion criteria for research participants.
- Exclusion criteria for research participants.
- Proposed methods for patient accrual including advertisement(s) etc.-patients may be identified as potential research participants through direct contact of the PI with his or her patients, collaboration with physicians of other medical specialties, contact with individual consultants, posted written notices, flyers, or other EC approved methods.
- If contact details are available the participant's personal physician/consultant should be notified before enrolling the participant.

6.10. Number of trials being handled by the Investigator

- Based on the number of trials being handled by the Investigator, EC will evaluate if the PI has sufficient time to efficiently conduct the study.

7. Type of Review

- All the proposals will be screened for their completeness by the Member Secretary/ Secretary, EC and will be considered for Full Board Review until a written request is submitted by the PI for Expedited review (AX 05- EC SOP 04/V 11) or Exemption from review (AX 06- EC SOP 04/V 11) along with the justification for the same. However the decision to accept the request for Exemption from review / Expedited Review will be made by the Member Secretary, EC.
- An investigator cannot decide that her/his protocol falls in the exempted category without approval from the EC.

7.1 Full Board Review:

- All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable populations and special groups shall be subjected to full review by all the members.
- When full board review is required the research proposal will be reviewed at a meeting at which a quorum of Committee member is present.
- It is important to remember that the Committee is constituted both as a Research and an Ethics Committee, and the purpose is to review and improve scientific quality in addition to human subject's protection, hence even if the study is of less than minimal risk, it may still need to be considered by the full EC.

7.2 Expedited Review:

- Should an amendment to a study-related document for a proposal previously approved through full review, be of an administrative in nature and not involving study design or safety criteria and there is no additional risk, can be considered for expedited review.
- For BA/BE studies expedited approval will be granted under circumstances where the protocol has been already approved by the Ethics Committee and the change is pertaining to only the unit & its study team where the study is being conducted, which still is one of the units belonging to the same client, coming under the Ethics Committee's jurisdiction.
- After determining that the Protocol/ Project or documents qualify for an expedited review, review may be made either by circulation for comments, telephone discussion, or meeting of 3-5 in-house members and may be provisionally approved in writing, by the Member Secretary of the Committee without calling a full meeting.
- The Member Secretary will inform other members of the amendment and his/her decision (Expedited approval). The decision will be ratified at the next full Committee meeting and this will be recorded and minutes maintained. If consensus cannot be reached, the Member Secretary will revert the proposal or the documents back to the PI for a full board review.

7.3 Exemption from review:

- Proposals which present less than minimal risk fall under this category as in situations such as research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Exceptions:
  i. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
  ii. When interviews involve direct approach or access to private papers
- The decision should be taken by the Member Secretary in consultation with the Chairman and an Expert from relevant field if the research protocol meets criteria of exempt review and the same will be informed to the PI. This should be informed to the members in the forthcoming EC meeting.

- In case the protocol does not fit in any of the above stated criteria, the Member Secretary / Chairman may keep the application for review and discussion at the full board meeting.
- In some circumstances, research which appears to meet low risk criteria may need to be reviewed by the EC. This might be because of requirements of:
  - The publisher of the research
  - An organization which is providing funding resources, existing data, access to participants etc.

AX 01- EC SOP 04/V 11

Reviewer Template for Clinical Trial Study

Institute		Date :
Protocol Number & Title:		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?		☐Yes ☐No
EC Reviewer's name		
1	No. of Study sites:	Globally: ____ and from India:___
2	Total No. of Participants:	Globally: ____ and from India:___
3	Target for our site:	
4	Age criteria:	
5	Duration of the Study:	
6	Review Type:	☐Full board ☐Expedited ☐Exemption
7	CTRI Registration:	☐Applicable ☐Not Applicable
8	Does this study require permission from regulatory authorities?	☐Yes ☐No If Yes ☐DCGI ☐ICMR ☐HMSC ☐other govt. Departments/ Agencies
9	Type of the Study (Interventional/ observational/ Genetic/ Others) :	
10	Does the study involve modified or new claims, namely, indications, dosage forms (including sustained release dosage form) and route of administration of already approved drugs and combination of two or more drugs	☐Yes ☐No
11	Objectives of the Study ☐Clear ☐Unclear	What should be improved?
12	Appropriateness of study design, work plan & structure to achieve the stated objectives:	Comment:

	☐Yes ☐No	
13	Whether the clinical trial on animals was done? If so what was the result submitted? ☐Yes ☐No ☐NA	
14	Need for Human Participants ☐Yes ☐No	Comment:
15	Methodology: ☐Clear ☐Unclear	What should be improved?
16	Background Information and Data about the molecule ☐Sufficient ☐Insufficient	Comment:
17	Availability of similar Study / Results ☐Yes ☐No	Comment:
18	Risks and Benefits Assessment ☐Acceptable ☐Unacceptable	Comment:
19	Scientifically Important, worthwhile and justifiable to conduct the study ☐Yes ☐No	Comment:
20	Does it addresses a health issue that is important for health and/or society? ☐Yes ☐No	Comment:
21	Aims, research questions and hypotheses built on and address gaps in the existing knowledge. ☐Yes ☐No	Comment:
22	Inclusion Criteria ☐Appropriate ☐Inappropriate	Comment:
23	Exclusion Criteria ☐Appropriate ☐Inappropriate	Comment:
24	Discontinuation and Withdrawal Criteria ☐Appropriate	Comment:

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

	☐Inappropriate	
25	Sufficient number of participants? ☐Yes ☐No	Comments
26	Control Arms (placebo, if any) ☐Yes ☐No	Comments
27	Community Consultation ☐Yes ☐No	Comments
28	Benefit to Local Communities ☐Yes ☐No	Comments:
29	Are qualifications and experience of the Participating Investigators appropriate? ☐Yes ☐No	Comments:
30	Based on the number of trials being handled by the Investigator, whether the PI has sufficient time to efficiently conduct the study? ☐Yes ☐No	Comments:
31	Facilities and infrastructure of Participating Sites ☐Appropriate ☐Inappropriate	Comments:
32	Provisions for monitoring the data to ensure the safety of participants ☐Yes ☐No	Comment:

Recommended Action

☐ Approval

☐ Modifications

☐ Disapproval

Reasons for disapproval:

☐ Deferred, if major clarifications are required before a decision can be made.

Name of the Reviewer : _____

EC designation : _____

Assigned Reviewer : Yes/No

Signature of the Reviewer : _____

Date : _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS ★ BANGALORE-560054 ★ ETHICS COMMITTEE

AX 02- EC SOP 04/V 11

Reviewer Template for Clinical Trial ICF

Institute		
Protocol Number :		Date :
Protocol Title :		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?		☐Yes ☐No
1	No. of Study sites:	Globally: ____ and from India:___
2	Total No. of Participants:	Globally: ____ and from India:___
3	Target for our site:	
4	Age criteria:	
5	Involvement of Vulnerable Participants	☐Yes ☐No
	If yes, check list for relevant vulnerable population has to be filled.	Comments ☐children, ☐pregnant or nursing women,& Fetus ☐mentally challenged/ mentally Differently abled group ☐participants with reduced autonomy ☐persons with mental illness ☐student or subordinates in hierarchical groups ☐Others, incapable of personally giving consent
6	Plan of Voluntary, Non-Coercive Recruitment of Participants spelt by the PI? ☐Yes ☐No	Comments
7	Are procedures for obtaining Informed Consent appropriate? ☐Yes ☐No	Comment:
8	Contents of the Informed Consent Document ☐Clear ☐Unclear	Comment:
9	Language of the Informed Consent	Comment:

	Document ☐Clear ☐Unclear	
10	Whether Informed Consent document is as per the regulatory requirement ☐Yes ☐No	Comment:
11	Contact Persons for Participants Mentioned? ☐Yes ☐No	Comment:
12	Privacy & Confidentiality ensured? ☐Yes ☐No	Comment:
13	Provision for Treatment of Study-Related Injuries ☐Appropriate ☐Inappropriate	Comment:
14	Provision for Compensation for out of pocket expenses ☐Appropriate ☐Inappropriate	Comment:
15	Provision for payments ☐Appropriate ☐Inappropriate	Comment:
16	Provision for Medical Support ☐Appropriate ☐Inappropriate	Comment:
17	Inducement for Participation ☐Unlikely ☐Likely	Comment:
18	Provision for post-trial access ☐Appropriate ☐Inappropriate	Comment:

Recommended Action

☐ Approval

☐ Modifications

☐ Disapproval

Reasons for disapproval:

☐ Deferred, if major clarifications are required before a decision can be made.

Name of the Reviewer : _____

EC designation : _____

Assigned Reviewer : Yes/No

Signature of the Reviewer : _____

Date : _____

AX 03- EC SOP 04/V 11

Reviewer Template for Legal Aspect of Clinical Trial

Institute		
Protocol Number :		Date :
Protocol Title :		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?		☐Yes ☐No
1	Clinical Trial Agreement – whether scrutinized and accepted? Whether it is fully assured by the sponsor that all the prevailing laws of India and international conventions in respect of subjects of clinical trial shall be scrupulously adhered to in the interest of safety, wellbeing and their rights?	Comments:
2	Trial Insurance– whether scrutinized and acceptable?	Comments
3	Whether provision for Compensation is made in case of clinical trial related injury/SAE/death which will be over and above the expenses incurred on the medical management of the trial subject?	Comments:
4	Provision for payments to patient for out of pocket expenses, whether any other contingent assistance is made available to the subject?	Comments:
5	Whether the format for informed consent has been designed and is it satisfactory? I) Whether the procedure of clinical trial has been explained in the consent form? II) Whether benefit over risk has been explained in the consent form? III) Whether vulnerable subjects are dealt with in the consent form? IV) Whether the subject is given express right to withdraw at his/her will at any stage of the clinical trial? V) Whether privacy and confidentiality of the subject regarding his/her personal information is adequately protected and informed? VI) Whether provision for Compensation in case of clinical trial related injury/SAE/death which will be over and above the expenses incurred on the medical management of the trial subject is explained in the consent form?	Comments:
6	Additional Comments, if any:	

Recommended Action

☐ Approval

☐ Modifications

☐ Disapproval

Reasons for disapproval:

☐ Deferred, if major clarifications are required before a decision can be made.

Name of the Legal Reviewer : _____

Signature of the Legal Reviewer : _____

Date : _____

AX 04- EC SOP 04/V 11

Reviewer Template for Risk Benefit Analysis

Institute	
Protocol Number :	Date :
Protocol Title :	
Principal Investigator/ Department	
Co – investigator(s)/ Department	
Sponsor/CRO	
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?	☐Yes ☐No

RISK DETERMINATION	BENEFIT ASSESSMENT	Recommended Action
☐Less than minimal risk ☐Minimal Risk ☐Minor increase over minimal risk or Low risk ☐More than minimal Risk or High risk	☐No prospect of direct benefit to individual subjects, but likely will yield generalizable knowledge about subject's disorder or condition ☐No prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society's understanding of the disorder or condition under study. ☐The prospect of direct benefits to individual subjects ☐No prospect of direct benefits to individual subjects, to science, or to society.	☐Approvable ☐Not Approvable ☐Approvable with modification/revision in the proposal

Name of the Reviewer : _____
EC designation : _____
Assigned Reviewer : Yes/No
Signature of the Reviewer : _____
Date : _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

Guidelines for assessing Risk

Less than minimal risk- Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.

Minimal Risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor increase over minimal risk or Low risk- Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

More than minimal Risk or High risk- Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

AX 05- EC SOP 04/V 11

Expedited Review Application Form

1. Principal Investigator's Name: _____
2. Department: _____
3. Project No. :_____
4. Title of Project: _____
5. Brief description of the project:

   _____

   _____

6. State reasons why expedited review from EC is requested? (Tick applicable)

   ____Risks to subjects is more than minimal

   ____Risks to subjects are minimal

   ____Research involving materials (data, documents, records, or specimens) that have been collected, for non-research (clinical) purposes

   Are children included in the study? _____Yes _____ No

   Does the research involve vulnerable population? _____Yes _____ No

   Any other reasons: _____

Principal Investigator's signature: _____ **Date** _____

Recommendations by the EC Member Secretary:

☐ Consider for expedited review

☐ Cannot be consider for expedited review, Reasons

_____

_____

Final Decision: ☐ Expedited Review ☐ For Full Board Meeting

Signature of the Member Secretary: _____ **Date** _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

AX 06- EC SOP 04/V 11

Review Exemption Application Form

1. Principal Investigator's Name: _____
2. Department: _____
3. Project No.: _____
4. Title of Project: _____
5. Brief description of the project (Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project):
6. State reasons why exemption from EC review is requested? (Tick applicable)
   - ☐ Audit of educational practices
   - ☐ Research on microbes cultured in the laboratory
   - ☐ Research on immortalized cell lines
   - ☐ Research on cadavers or death certificates which reveals no identifying personal data
   - ☐ Analysis of data freely available in the public domain
   - ☐ Any other (please specify) ----------

Principal Investigator's signature: _____ **Date** _____

Recommendations by the EC Member Secretary:

☐ Exemption

☐ Cannot be exemption, Reasons

_____

☐ Discussion at Full Board

Signature of the Member Secretary: _____ **Date** _____

Final Decision:

☐ Exemption

☐ Cannot be exemption, Reasons

_____

_____

Final Decision at Full Board meeting held on: _____

Signature of the Member Secretary: _____ **Date** _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

AX 07- EC SOP 04/V 11

Assigned Reviewer for Clinical Trial

Institute:		
Date:		
Protocol Number & Title :		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
1	Duration of the Study	
2	Status:	☐New ☐Revised ☐Amendment
	If Amendment	☐Major ☐Minor
3	Name of assigned EC Reviewer's	
4	Review Type	☐Full board ☐Expedited ☐Exemption

Signature of the Member Secretary: _____ **Date** _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Ethics Committee Meeting- Agenda Preparation, Meeting Procedures, Decision Making, Recording of Minutes, Communicating the decision and Activity Report

SOP Number	EC SOP 05/V 11
Effective Date	28 May 2019
No of pages	01 to 10
Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The purpose of this SOP is to elaborate administrative process and provide instructions for preparation, distribution of meeting agenda, meeting procedures including decision making, making minutes, and communicating the decision to the Principal Investigator.

2. Scope

This SOP applies to procedures to conduct the EC meeting.

3. Responsibility

It is the responsibility of the Member Secretary, Secretary and administrative staff to prepare for the EC meeting and follow the SOP for decision making.

4. Detailed Procedure

- The EC will meet at once in a month or more frequently as per requirement (subject to change with prior notification), to enable detailed review of all proposals scheduled for the convened meeting.
- The EC meeting roaster for the year will be prepared in January every year and will be circulated to all concerned. In the event that the timing is unsuitable, the meeting could be rescheduled by the Member Secretary in consultation with the Chairman of the Ethics Committees.
- The Member Secretary may recommend to the Chairman to call for an extra-ordinary/ emergency meeting, even at a short notice, in the interest of the trials/ study/ safety of study participant/ research proposal for review and the same will be recorded in the minutes of the meeting.

4.1. Before Full Board EC meeting

- The Secretary, EC shall prepare an agenda, schedule protocols on the agenda on a first come first basis and send this to the members of the EC before the meeting.
- The documents will be distributed to all EC members as per section 4.2 of EC SOP- EC SOP 03/V 11.
- Each member of the EC shall receive copy of the protocols by either soft/electronic mail or hard copy with all submitted documents along with the agenda before the meeting.
- The proposal will be reviewed in detail by members of the Committee for scientific and ethical considerations, and their views will be shared at the meetings.
- EC members are encouraged to seek clarification from researchers directly or via the Secretary, EC before the EC meeting so that conclusive decisions can be facilitated.
- If expert opinion is thought necessary by the members a suitable person will be invited for the meeting.

4.2. Preparation for the meeting

- Reserve the meeting room on the scheduled meeting date and time of EC meeting.
- Ensure that the room, equipment (projectors, laptop, etc) and facilities are available in good working conditions.
- All original files of studies on the agenda are kept in the meeting room for ready reference before the meeting.

- E-copy of SOPs, New Drugs and Clinical Trials Rules, 2019, ICMR guidelines, ICH-GCP, Indian GCP are kept available for ready reference.
- Secretary will inform the scheduled meeting date and time to the Principal Investigators.
- The meeting will be re-scheduled or canceled if it becomes apparent that meeting requirements (quorum, sufficient expertise) will not be met.

4.3. Conduct of Meeting

- The members should gather in meeting room on scheduled time.
- The Committee meeting shall be presided over by the Chairman who shall lead all deliberations and discussions pertinent to review of the study/research proposals, office matters, etc. in accordance with the agenda.
- The Chairman before beginning the discussion will:
  - ✓ Ensure that the quorum requirements are met
  - ✓ Request to declare conflict of interest (financial or non-financial) either verbally or written on any protocol for discussion.
  - ✓ If an EC member has conflict of interest involving a project then he / she should declare the same, before the meeting commences and should abstain him/ herself from the discussion on the same. This should be recorded in the minutes.
- The projector is used for projection of agenda.
- The EC may invite investigators to attend the full board meeting related to their studies, and clarify doubts, if any
- The meeting proceeds in the sequential order of the agenda; however the Chairman may change the order, if the situation so demands.
- The Chairman may permit any item for review/discussion/ decision aside from the agenda during the meeting. Such an item, when permitted by the Chairman shall be deemed to be part of the agenda and any decision on the included item shall have the same effect and be as binding as any other original item on the agenda.
- The Member Secretary will request assigned reviewer to discuss the research study. The reviewer should submit the duly filled study review form, if applicable.
- In case the reviewer cannot attend the meeting (informed to the committee before) Member Secretary/ any other EC member may brief the EC about the research study and also discuss the written comments/duly filled study review form.
- Amendments/SAEs/Periodic Study status report/Continuing Annual report /Protocol Deviations/ Closeout report Documents will ordinarily be reviewed by Member Secretary/ Basic Medical Scientist.
- During the initial or continuing review of the research, material provided to EC members will be considered confidential and the board members will assure the confidentiality of the information provided to them.
- The Member Secretary and Secretary, EC is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers.

4.4. Decision-making:

- EC completes the adequate review of the research studies submitted. The committees will review new studies, amendments, continuing annual review of ongoing studies, SAE reports, Protocol Deviations, close out reports and any other documents through a scheduled agenda.
- A member should voluntary withdraw from the meeting during the decision procedure concerning an application where there is a conflict of interest or a conflict of interest arises and this should be indicated to the Chairman in writing prior to the review of the application and recorded in the minutes. The EC shall not approve a research protocol where a conflict of interest is not eliminated, and it has the final authority to determine whether a conflict of interest has been eliminated appropriately.
- Decision may only be taken when sufficient time has been allowed for review and discussion of study in the absence of non-members (e.g., the investigator, independent consultants) from the meeting, with the exception of EC staff. Members will discuss the various issues before arriving at a consensus decision.
- All decisions will be taken at only convened meetings where quorum is complete and not solely by circulation of project proposals.
- Only members who participate in the review will participate in decision making. The Independent consultants will only offer their opinions.
- Decisions will be arrived by consensus/unanimous or majority opinion amongst the voting members of EC after discussions, where possible; when a consensus is not possible voting will be done. Voting may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairman. Only those Ethics Committee members who are independent of the investigators team and sponsors of the trial and who are present in the meeting have voting rights.
- In the event of a vote, although the names of members who voted for and against the project may be noted, this information will not be made public knowledge nor will it be documented in the minutes to avoid coercion and inducements.
- The Chairman is the concluding authority in EC voting and final decisions, he/ she will sign the minutes.
- For clinical trial the Decision Form for Initial Review of Clinical Trial (AX 01- EC SOP 05/V 11) will be filled and the final decision of the EC will be mentioned and signed by the chairman. The document will be placed in the respective clinical trial file.

4.5. After the EC meeting

- The Member Secretary and Secretary will compile the proceedings of EC meeting in English in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes.
- The basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution must be recorded.
- The minutes of the meeting finalized by the Member Secretary will be forwarded to the chairman by the Secretary and Chairman's approval will be taken, preferably within two weeks and will be signed by Chairman and Member Secretary.
- After Chairman's approval, minutes of the meeting will be circulated to the members. The minutes of the EC meeting will be ratified in the subsequent EC meeting.

- The Study Team Member's non participation in the decision making/voting process will be recorded in the minutes and also in the response letter from the EC.
- Place the original version of the minutes in the agenda and minutes file.

4.6. Communicating the decision:

- All the communications will be made in English, and care will be taken that the decision, action and recommendation are clearly defined. Where ever possible a written document will be maintained for the communication between all the involved stake holders to have a transparency in action however care will be taken to maintain the confidentiality of these documents and communications. A copy of these communication will be retained in EC office.
- In routine practice EC will directly communicate with the PI, Institution and Regulatory authority. Under certain circumstances where the need arises EC may directly communicate with the Participant and Sponsor/ CRO.
- Communication records of/to the Committee shall contain, but not limited to date of communication, study information (e.g. sponsor, protocol number, investigator), name of person contacted, contact address, summary of communication made, notation of any follow-up necessary and signature of individual(s) making the record.
- The decision of EC which is approved by Chairman, will be communicated by the Member Secretary to the Principal Investigator/other stakeholder in writing after minutes of the meeting are finalized, preferably within a two weeks' time of the meeting at which the decision was made.
- The Committee will give its opinion on the project in one of the following ways:
  1. Approval
  2. Conditional Approval e.g. in case the DCGI approval letter is not available at the time of initial submission, conditions related to study criteria etc.
  3. Revise the proposal e.g. Specific suggestions for modifications for a repeat review or advise appropriate steps.
  4. Disapproval supported by clear stated reasons.
  5. Discontinuation/termination of a previously approved project.
- As per New Drugs and Clinical Trials Rules, 2019, the EC communication of the decision to PI for clinical trials will include, but is not limited to, the following (AX 02- EC SOP 05/V 11):
  1. Name of Investigator.
  2. Title of the Clinical Trial.
  3. Date of meeting.
  4. Number and names and specific identification number, version numbers/dates of the documents reviewed.
  5. Number of participants to be accrued
  6. Time of meeting.
  7. Place of meeting.
  8. Members present in the EC meeting with their name and designation.
  9. Decision of Ethics Committee.
  10. Any suggestions by the EC.

11. In case of a positive decision requirement of EC to report progress of study, any SAE occurring, any change in the protocol / informed consent form / patient information , copy of final report, any unforeseen circumstances, the termination of the study, or significant decisions by other IRBs or the Drug Controller General of India.
12. In case of a conditional decision, any requirements by the EC, including suggestions for revision and the procedure for having the application re-reviewed.
13. In the case of a negative decision, clearly stated reason(s) for the negative decision.

- The participant should be recruited into the trial only after written approval is received from the EC and applicable regulatory authority.
- The decision for amendments in protocol or any other study related documents of clinical trial, will also be documented and communicated in the same manner, as mentioned above.
  - If the EC approves the amendments, the Member Secretary will communicates this decision to the PI.
  - If the EC does not approve the amendments, the Member Secretary should immediately notify the investigator in writing of the decision and the reason for not approving the amendment.
  - If the EC recommends or suggests modifications to any of the documents, or the amendments, the Member Secretary will sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to EC.

4.7. Activity Report

- April every year, the Secretary, EC shall prepare an Annual Report on the working of the Board including the details of the number of meetings held, the number of proposals received, the number considered, approved or approved with modification, rejected. The Annual Report with approval of the Member Secretary shall be sent to the CE-GEF.

References

- EC SOP- EC SOP 03/V 11- Application procedure

AX 01- EC SOP 05/V 11

Decision Form for Initial Review of Clinical Trial

Protocol Number & Title :		
Principal Investigators/ Department		
Sponsor/CRO		
1.	Name of assigned EC Reviewer's	
2	Review Type	☐Full board ☐Expedited ☐Exemption
3	Quorum status	☐Appropriate ☐Inappropriate ☐NA
4	Conflict of interest of any members	☐Yes ☐No
	If yes,	Name: Type of Conflict:
5	Comments or suggestions if any (Attach extra sheets, if necessary):	
6	Member Secretary decision in case of expedited review or exemption from review.	

Final EC Decision:

☐ Approved

☐ Conditional Approval

☐ Disapproved

Reasons for disapproval:

☐ Deferred, until clarification/correction is provided.

Approval given for a period of: _____ Years

Continuous review to be done at:

Periodic study status to be submitted at:

☐ Quarterly

☐ Six monthly

☐ Annually

Final Decision at Full Board meeting held on:

Name of the Chairman : _____

Signature of the Chairman : _____ **Date** _____

AX 02- EC SOP 05/V 11

Approval Letter Format

To,
Dr._____
M S Ramaiah Medical College and Hospitals
Address

Ref: Project No and Title
Subject: Ethics committee approval for the referenced study and related documents

Dear Dr.
The Ethics Committee, M S Ramaiah Medical College and Hospitals, has reviewed XX copies (no of copies) of the following documents vide your submission letter (dated) for the above referenced study:

- Study protocol (including protocol amendments), dated_____, version no(s).
- Patient information sheet and informed consent form (including updates if any) in English and/Vernacular language.
- Investigator's Brochure, dated_____, version no._____
- Case Record Form
- Proposed methods for patient accrual including advertisement(s)etc. proposed to be used for the purpose.
- Current CVs of Principal investigator, Co-investigators
- Package inserts
- Insurance policy/compensation for participation and for serious adverse events occurring during the study participation.
- Investigator's Agreement with the sponsor.
- Investigator's undertaking.
- DCGI/DGFT approval
- Clinical Trial Agreement (CTA)

The Ethics Committee of M S Ramaiah Medical College and Hospitals reviewed and discussed your application along with the above documents in the EC meeting held on _____ (Date), and after due consideration has decided to approve the study to be conducted under your supervision at M S Ramaiah Medical College and Hospitals, in accordance to the EC approved protocol and in compliance with regulations and guidelines as applicable.
The study is approved in its present form for ____years from the date of approval. The Principal Investigator should submit continuing annual review report failing which the EC shall revoke the EC approval. In order to ensure that there is no lapse in the EC approval period, it is mandatory to submit study continuing annual review report within 1 month of the due date (i.e. 11 months from the date of approval) prior to lapse of study validity.

Kindly note that EC has approved recruitment/review of ____ participants in this study, if the number of subjects recruited/reviewed are more kindly notify the Ethics Committee. Ethics Committee also approves the following methods of patient accrual:

1. XXXXXX
2. YYYYYY

The following members of the Ethics Committee were present at the meeting held on Date _____, Time at Place _____

Sl. No.	Name	EC Designation	Voted / Not- Voted	Role
1.				
2.				
3.				

It is here by confirmed that neither you nor any of the study team member have participated in the voting / decision making procedure of the committee.

The study should be initiated only after notifying EC about:

- Registration of the study with Clinical Trials Registry India (CTRI) (if applicable).
- Finalized Clinical Trial Agreement
- DCGI approval (if applicable).

The Ethics Committee expects to be informed about initiation of the study at our center, any Serious Adverse Events (SAEs) occurring in the course of the study, any deviation/violation/waiver in the protocol, any changes in the protocol and patient information/informed consent and study reports to be given at least every six months from the date of approval. Also a copy of the study completion/close out report should be submitted to the EC.

We confirm that the Ethics Committee operates as per ICH GCP guidelines, Indian GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019.

Thanking You,
Yours Sincerely,
Member Secretary,
EC.

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Review of Amended protocol/ Protocol related documents

SOP Number	EC SOP 06/V 11
Effective Date	28 May 2019
No of pages	01 to 09
Superseded Version Number & Date	V 10 Amendment 01 & 29 Dec 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The purpose of this procedure is to describe how protocol amendments or any other amendments in study documents are reviewed by the EC.

2. Scope

This SOP applies to amended study protocols/ documents that are submitted for EC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the EC.

3. Responsibility

It is the responsibility of the EC secretariat to manage amendments to protocol and other study documents.

4. Detailed Procedure

4.1 Receipt and verification of submitted package for protocol or other study related documents amendments

- The amendment documents along with the submission letter and Amendment Reporting Form (AX 01- EC SOP 06/V 11) will be forwarded by the PI, at least three weeks in advance to the next scheduled meeting.
- The Submission letter for amendment along with the documents will be received by Member Secretary/Secretary who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 11.
- The Member Secretary/Secretary will confirm that the changes or modifications in the amended version are underlined or color highlighted along with detailed summary of changes.
- The Secretary will check for completeness of the submission and inform the Principal Investigator/ team to submit the required documents at the earliest, if any of the documents are missing/ incomplete.

4.2. Determine whether full review or review by Member Secretary

- The Member Secretary, EC, classifies the amendments into minor or major and tables the major amendments on the agenda of the subsequent scheduled meeting.
- Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) and minor changes in previously approved study documents like renewed insurance policy, DCGI approvals and documents of administrative nature will be noted/received by the Member Secretary, and not tabled in EC meeting.
- The major amendments/changes in study documents like Protocol, ICF, IB and documents used for the participant will be tabled on the agenda of the subsequent scheduled meeting. The amendments and other documents which need full board review are processed according to the EC SOP 04/V 11.
- Each clinical trial amendment will be assigned to one of the Scientific Member of the committee by Member Secretary based on the area of expertise, who will be considered as assigned reviewer for the study amendment and will be documented in the Assigned Reviewer for Clinical Trial (AX 07-EC SOP 04/V 11).

- Assigned reviewer will review the study documents and will give his/her comments on the study using the Review Form for Clinical Trial Amendment Documents (AX 02-EC SOP 06/V 11).
- Amendments in Protocol, IB, ICF and other subject related documents will be considered as major amendment and should be submitted for approval except when document has only administrative changes, as mentioned below and provided that the basic protocol, IB, ICF's and other participant related documents have been reviewed and approved by EC earlier. Administrative changes in these documents which can be considered as minor amendment and can be notified to EC member who has been assigned as the reviewer of the study are mentioned below:
  - ✓ Change in EC/ sponsors name and contact details
  - ✓ Typographical errors
  - ✓ Grammatical corrections
- The amended study documents should be approved by the EC prior to making any changes in study procedures.

4.3. Distribution to EC members and storage

- After the last day of submission is over, one set (hard or soft/electronic copy) of the submitted amendment documents will be sent to the assigned reviewer along with Review Form for Clinical Trial Amendment Documents (AX 02-EC SOP 06/V 11), ensuring sufficient time for review. The remaining set of documents (hard or soft/electronic copy) will be distributed to all the EC members.
- For clinical trials one hard copies will be stored under controlled access storage in EC office, in the appropriately labelled (in serial order) respective study EC submission file.
- For Academic trials, after the last day of submission is over, the amended protocol and related documents will be distributed to all the EC members and one hard copy of all the proposals discussed in a particular meeting will be stored meeting wise in common EC file.

4.4. Review and decision of protocol or other study related documents amendments

- The Assigned Reviewer will review the amended documents and give his/her comments in full board meeting.
- The committee will assess if, the changes affect the scientific validity of the study, Patient Safety, Risk Benefit Assessment or the expectedness of SAE (EC SOP 04/V 11).
- The committee will follow the steps as mentioned in section 4.4 of EC SOP 05/V 11 and the final decision will be taken.
- The Review Form for Clinical Trial Amendment Documents (AX 02- EC SOP 06/V 11) will be filled by the assigned reviewer and the final decision of the EC will be documented in Decision Form for Clinical Trial Amendment (AX 03- EC SOP 06/V 11) and signed by the chairman. The document will be placed in the respective clinical trial file.

4.5. Communicating the Decision

- If the EC approves the amendments, the decision is communicated to the PI (AX 04- EC SOP 06/V 11).
- If the EC does not approve the amendments, the Member Secretary should immediately notify the investigator in writing of the decision and the reason for not approving the amendment.

- If the EC recommends or suggests modifications to any of the documents, or the amendments, the Member Secretary sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to EC.

References

- EC SOP- EC SOP 03/V 11 - Application Procedures
- EC SOP- EC SOP 04/V 11- Review Procedures
- EC SOP- EC SOP 05/V 11- Ethics Committee Meeting- Agenda Preparation, Meeting Procedures, Decision Making, Recording of Minutes, Communicating the decision and Activity Report

AX 01- EC SOP 06/V 11

Amendment Reporting Form

Protocol Number & Title		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
Date of EC Approval		
Study initiation date		
1	Enrollment Status	☐Ongoing ☐Completed ☐Stopped
2	Have the changes modifications in the amended versions been highlighted/ underlined?	☐Yes ☐No
3	Nature of amendment	☐Major ☐Minor
4	Does this amendment entail any changes in Informed Consent(ICF)	☐Yes ☐No
	If yes, whether amended ICFs are submitted?	☐Yes ☐No
	If yes, Specify ICF Version No. & Date and its EC approval and If no specify the reason	
5	Does the revision entail any change in the Risk vs Benefit?	☐Yes ☐No
6	Amendment Document details	

Summary List of Changes

Name of Amendment document	Revised version/Date	Section and page no	Provision in Existing version	Change(s) in the new version	Risk & Benefit Assessment/Justification

Principal Investigator Signature

Date

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS BANGALORE-560054 ETHICS COMMITTEE

Review of Amended protocol/ Protocol related documents

AX 02- EC SOP 06/V 11

Review Form for Clinical Trial Amendment Documents

Protocol Number & Title		
Principal Investigator/ Department		
Co – investigator(s)/ Department		
Sponsor/CRO		
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators?		☐ Yes ☐ No
Amendment Document details (in brief)		
EC Reviewer's name		
1	Review Type:	☐Full board ☐Expedited ☐Exemption
2	Does the amendment adversely affect the safety of the research participants	☐Yes ☐No
	If yes, is it	☐Acceptable ☐Unacceptable
4	Does the amendment changes the Risk Benefit Assessment of the study	☐Yes ☐No
	If yes, is it	☐Acceptable ☐Unacceptable
5	Does the amendment increases the Expectedness of SAE in the research participants	☐Yes ☐No
	If yes, is it	☐Acceptable ☐Unacceptable
6	Is the justification given for the amendment acceptable	☐Yes ☐No

Recommended Action

☐ Approval

☐ Modifications

☐ Disapproval

Reasons for disapproval:

☐ Deferred, if major clarifications are required before a decision can be made.

Name of the Reviewer : _____

EC designation : _____

Signature of the Reviewer : _____

Date : _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

AX 03- EC SOP 06/V 11

Decision Form for Clinical Trial Amendment

Protocol Number & Title :		
Principal Investigator/ Department		
Sponsor/CRO		
1.	Name of assigned EC Reviewer's	
2	Review Type	☐Full board ☐Expedited ☐Exemption
3	Quorum status	☐Appropriate ☐Inappropriate ☐NA
4	Conflict of interest of any members	☐Yes ☐No
	If yes,	Name: Type of Conflict:
5	Comments or suggestions if any (Attach extra sheets, if necessary):	
6	Member Secretary decision in case of expedited review or exemption from review.	

Final EC Decision:

☐ Approved

☐ Conditional Approval

☐ Disapproved

Reasons for disapproval:

☐ Deferred, until clarification/correction is provided.

Final Decision at Full Board meeting held on:

Name of the Chairman : _____

Signature of the Chairman : _____ Date _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE

AX 04- EC SOP 06/V 11

Approval Letter Format for Amendment Document

To,
Dr._____
M S Ramaiah Medical College and Hospitals
Address

Ref: Project No and Title
Subject: EC approval for study related documents/ amendment documents
Dear Dr.

The Ethics Committee, M S Ramaiah Medical College and Hospitals, has reviewed XX copies (no of copies) of the following documents vide your submission letter (dated) for the above referenced study:

- XXXXX

The Ethics Committee of M S Ramaiah Medical College and Hospitals reviewed and discussed your application along with the above documents in the EC meeting held on _____ (Date), and after due consideration has decided to approve same.

The following members of the Ethics Committee were present at the meeting held on Date _____, Time at Place _____

Sl. No.	Name	EC Designation	Voted / Not- Voted	Role
1.				

It is here by confirmed that neither you nor any of the study team member have participated in the voting / decision making procedure of the committee.

We confirm that the Ethics Committee operates as per ICH GCP guidelines, Indian GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019.

Thanking You,
Yours Sincerely,
Member Secretary,
EC

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Continuing Review of Study Protocols

SOP Number	EC SOP 07/V 11
Effective Date	28 May 2019
No of pages	01 to 13
Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS BANGALORE-560054. ETHICS COMMITTEE

1. Purpose

The purpose of continuing review is to monitor the progress of the study which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting continuing review of studies involving human participants at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, EC may choose to review the study more frequently and the decision is taken during the EC meeting wherein the project is finally approved and the same will be documented.

3. Responsibility

It is the responsibility of the all Principal Investigator's to send Study status Report for all his approved studies at least every six months. EC is primarily responsible for reviewing the study progress, the occurrence of unexpected events, protocol deviations or problems, and the rate of accrual of participants.

4. Detailed Procedure

4.1. For Clinical trials Committee expects from the Principal Investigator

- To comply with all directions of the EC.
- Site should be initiated only after the written approval is granted by the EC to the Principal Investigator and regulatory approvals (if applicable) and the site initiation should be notified to EC.
- Notify the CTRI registration number before the first patient is screened, wherever applicable.
- Report each serious adverse event occurring at the site with regard to the study within the timelines set by New Drugs and Clinical Trials Rules, 2019, ICH-GCP, Indian GCP, ICMR guideline and any other applicable regulatory guidelines and also the details of SAE at other centers (CIOMS).
- All amendments in protocol/ ICF/ IB or any study related document, procedures as well as patient safety related information available related to EC approved protocols must be submitted to EC for review and opinion.
- Report all the deviations, violations from the approved Study Protocol in timely manner.
- Submit filled Participant Feedback Form (AX 01- EC SOP 07/V 11, translation in local languages available in EC Office) for each participant after he/she has been randomized into the study.
- Submit periodic study status report (AX 02- EC SOP 07/V 11) of the Clinical Trial every six month or more frequently if so directed, from the date of approval of the study in a timely manner. After receiving EC approval, even if site is not initiated periodic study status report must be submitted mentioning reasons for not initiating the site. Any PI who fails to submit the report for review within the stipulated time, will have to clarify the delay in writing, this will be forwarded to the Chairman, EC.

- Submit the continuing annual review application (AX 03- EC SOP 07/V 11) well in advance i.e. 11 months after EC final approval and at least annually.
- Submit the justification for approval to restart studies discontinued earlier.
- Kept informed of discontinuation with reasons and a final study completion report (AX 07- EC SOP 07/V 11) should be submitted at the time of study close out.
- In case of premature termination / Suspension / Discontinuation of study, EC should be informed and the notification should include the reasons for termination along with the summary of results conducted till date.

4.2. For Academic trials Committee expects from the Principal Investigator

- To comply with all directions of the EC.
- Study should be started only after the written approval is granted by the EC to the Principal Investigator.
- Register the study with CTRI, if applicable
- All amendments in protocol, ICF or any study related document, must be submitted to EC for review and opinion.
- Submit study report to the Department of Research and Patency (DRP) on an annual basis or more frequently if so directed, from the date of approval of the study in a timely manner.
- Keep DRP informed of study completion and discontinuation with reasons.

4.3. EC continuous review process

- The SAE at site and those reported from other centres (CIOMS) will be reviewed on regular basis as mentioned in the EC SOP- EC SOP 08/V 11.
- The protocol deviations, violations reported for the approved Study Protocol will be reviewed on regular basis as mentioned in the EC SOP- EC SOP 09/V 11.
- The periodic study status report will be reviewed by the Member Secretary.
- All the approved clinical trial protocols will be reviewed annually. The continuous annual review report will be received by Member Secretary/ Secretary who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 11. The Member Secretary will review the application using Check list for review of Study Continuous Review Report (AX 04- EC SOP 07/V 11) may call upon the Principal Investigators to present the progress of their study in the next scheduled EC meeting from time to time. Member Secretary will decide if the report requires full board/ Expedited Review/ Exemption from review.
- If the Investigator will miss to send the continuous annual review report within the required timeline and reminder will be sent by the Secretariat to the investigator (AX 06- EC SOP 07/V 11).
- The continuous annual review report of clinical trial will be placed on the agenda of the forthcoming EC meeting for discussion and necessary opinion or suggestions. After reviewing the continuous review report of the study, the EC can give the decision as, no objection to continue the study; no objection with recommendations or discontinuation. The EC decision will be notified to the PI in writing (AX 05- EC SOP 07/V 11).

- EC can decide to reverse its positive decision (terminate or suspend) on a study in the following circumstances:
  - Receiving information that may adversely affect the benefit/risk ratio.
  - When research is associated with unexpected serious harm to participants.
  - When the research is not conducted in accordance with Ethics Committee requirement.
  - When EC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

  The decision will be documented in the Minutes of the meeting and will be communicated to the PI. The EC will also review the process of informing the participants of the termination and also the procedure of follow up of the participants with AE/ SAE.
- The Participant Feedback Form will be received by Member Secretary/ Secretary who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 11 and will be forwarded to the Lay person/Social Worker for their review and the same will be discussed in the EC meeting for any comments and suggestions.
- All clinical trial study completion reports submitted will be received by Member Secretary/ Secretary who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 10. The complete report will be forwarded to the Member Secretary, who may call upon the Principal Investigators to present the report of their study in the next convened EC meeting. In the meeting if the report is found to be satisfactory, the study will be considered as closed. In case of any queries regarding the final report, the committee will ask the investigator to attend the next convened EC meeting to make a presentation of their work and answer queries.
- For academic trial the study annual report, closeout report and other communication of continuous review will be maintained by the DRP. EC may ask DRP in-charge to give the academic study status when required.

References

- EC SOP- EC SOP 03/V 11- Application Procedures
- EC SOP- EC SOP 08/V 11- Review of Serious Adverse Event
- EC SOP- EC SOP 09/V 11- Review of Protocol Deviation/Non-Compliance/ Violation/ negligence

AX 01- EC SOP 07/V 11

Participant feedback form

Protocol Number:
Principal Investigator:
Subject Number and Initial:
Age/Sex:

Sl. No.	Criteria	Response
1.	Did you understand the study and gave a voluntary consent?	____Yes ____No
2.	Are you aware that you are part of clinical Trial?	____Yes ____No
3.	Whether detailed instructions were given on the use of the Investigational Product?	____Yes ____No
4.	Were you aware about the Placebo arm (Dummy drug)?	____Yes ____No ____NA
5.	Are you aware of the common adverse event reported in the study?	____Yes ____No
6.	Are you aware whom to contact in case of questions related to the study, health related issue, Adverse Event or Serious Adverse Event?	____Yes ____No
7.	Are you aware whom to contact in case of questions related to your rights in the study?	____Yes ____No
8.	Have you been updated and have you understood the risk benefits associated with the study?	____Yes ____No
9.	Are you satisfied with the care taken by the investigator and team?	____Yes ____No
10	Comments, if any	

Patient Name & Signature/Thumb Impression _____ Date _____

LAR Name & Signature _____ Date _____

Principal Investigator Signature _____ Date _____

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

AX 02- EC SOP 07/V 11

Periodic Study Status Report Format

(The details to be provided by PI)	
Protocol No. & Title:	
Principal Investigator:	
Sponsor/CRO:	
EC approval Date	
Study Initiation Date	
Enrollment Status	☐Ongoing ☐Completed ☐Stopped
Last annual report date	
No. of study participants approved by EC	
No. of study participants Screened since last report	
No. of study participants Randomized/ Recruited since last report	
Total no. of study participants Screened till date	
Total no. of study participants Randomized/ Recruited till date	
Total no. of screen failure till date	
Total no. of study participants completed the study	
Total no. of study participants ongoing	
AEs at our center (Total number, type and outcome)	
SAEs at our center (Total number, type, outcome and compensation status)	
Whether all SAEs intimated to the EC (Yes/No)	
No. of patients withdrawn/discontinued	
Reasons for withdrawal/discontinuation	
Protocol deviations/violations(Number and nature)	
Whether all PD's intimated to the EC (Yes/No)	
Signature of PI Date:	

AX 03- EC SOP 07/V 11

Continuing Annual Review Application Form

Protocol No. & Title:	
Principal Investigator	
Sponsor/CRO	
EC approval Date	
Validity of EC approval	
CTRI No	
Date of last periodic status report	
Date of last continuous annual review report	
Duration of study (overall)	
Study Initiation Date (If 'Not Initiated' state Reason)	
Date of accrual of first subject/sample	
Enrollment Status	☐Ongoing ☐Completed ☐Stopped
No. of study participants approved by EC	
No. of study participants Screened since last report	
No. of study participants Randomized/ Recruited since last report	
Total no. of study participants Screened till date	
Total no. of study participants Randomized/ Recruited till date	
Total no. of screen failure till date	
Total no. of study participants completed the study	
Total no. of study participants ongoing	
AEs at our center (Total number, type and outcome)	
SAEs at our center (Total number, type, outcome and compensation status)	
Whether all SAEs intimated to the EC (Yes/No)	
No. of patients withdrawn/discontinued	
Reasons for withdrawal/discontinuation	
Protocol deviations/violations (Number and nature)	

Whether all PD's intimated to the EC (Yes/No)	
Have there been any Protocol amendments since last Continuous Annual Review report/ Initial Approval	☐Yes ☐No
If 'YES', please provide details	• Amendment No. and version details: • Date of submission: • Date of EC Approval
Have any Informed Consent documents been amended since last continuous Review report	☐Yes ☐No
If 'YES', please provide details	• Amendment No. and version details: • Date of submission: • Date of EC Approval: • Whether all the patients were reconsented on the amended ICF on the next scheduled visit
Was the study Monitored by Data Monitoring Committee (DMC)?	☐Yes ☐No
If Yes, is the DMC report available?	☐Yes ☐No ☐NA (If 'YES', submit as an attachment)
Are you applying for extension for the study approval	☐Yes ☐No
If yes, period of extension requested?	
Signature of PI Date:	

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

AX 04- EC SOP 07/V 11

Check list for review of Study Continuous Review Report

Protocol No. & Protocol Title:	
Principal Investigator:	
Sponsor/CRO:	
Documents submitted	
Date of EC approval & initiation details provided	☐Yes ☐No ☐NA
Last annual report date provided	☐Yes ☐No ☐NA
Details on number study participants Screened/ Randomized/ Recruited/screen failure provided	☐Yes ☐No ☐NA
Details on number study participants completed/ ongoing in the study provided	☐Yes ☐No ☐NA
Details of AEs at our center provided	☐Yes ☐No ☐NA
Details of SAEs at our center provided	☐Yes ☐No ☐NA
Details of Protocol deviations/violations at our center provided	☐Yes ☐No ☐NA
Details of No. of patients withdrawn/discontinued at our center provided	☐Yes ☐No ☐NA
Details of Amendments in the study are provided	☐Yes ☐No ☐NA
Details of DMC provided	☐Yes ☐No ☐NA
Review Type	☐ Full board ☐ Expedited ☐ Exemption

Remarks:

Signature of Member Secretary with date: _____

EC Decision on the Continue Review Report

☐Approved and the project can be continued without any modifications

☐Modifications recommended - requiring protocol resubmission

State the recommendations:

☐Protocol should be discontinued

State the reasons for discontinuation:

Date of Full Board discussion:

Signature of Chairman with date: _____

AX 05- EC SOP 07/V 11

Reminder letter to investigator for submitting Continuing Annual Review Application Form

Name of Principal Investigator:-
Address of Principal Investigator:-
Ref: - Project No & Title: XXXXXX

The above referenced project was approved by the EC on XXXXXXX and is due for continuing annual review by the EC.

Kindly submit the continuing annual review application on or before_____. In case the projects have been completed / terminated, kindly complete the appropriate forms and submit to EC on or before (date).

Thanking you for your co-operation,

Yours truly,

Signature with date
Secretary, EC

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE

AX 06- EC SOP 07/V 11

EC Continuing Annual Review Opinion Letter

To,
Principal Investigator,
MSRMCH

Ref: Project No./Title

Dear Dr.
The continuing annual review application for the above referenced project was and discussed during the Ethics Committee (EC) meeting held on date (place) (time)

The following members of the Ethics Committee were present at the meeting held on Date _____, Time at Place _____

Sl. No.	Name	EC Designation	Voted / Not- Voted	Role
1.				
2.				

EC comments were as follows:

The Ethics Committee of M S Ramaiah Medical College and Hospitals reviewed and discussed your application in the EC meeting held on _____ (Date), and after due consideration has decided to approve the continuation of the study/approved with modifications/Not approved

It is here by confirmed that neither you nor any of the study team member have participated in the voting / decision making procedure of the committee.

Thanking you,

Yours faithfully,

Member-Secretary,
Ethics Committee

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * ETHICS COMMITTEE * Date: BANGALORE-560054.

AX 07- EC SOP 07/V 11

Study Completion/Close out Report Format

(To be Filled by PI)	
Protocol No. Protocol Title: Principal Investigator:	
Phone number, email address	
Sponsor/CRO	
EC Approval date	
Study Initiation Date	
Duration of the study	
Total no. of study participants screened	
Total no. of participants randomized	
Total no. of Screen failure	
No. of patients withdrawn/Discontinued	
Reasons for withdrawal/discontinuation	
No of SAEs at our center (Total number, type, outcome and compensation status)	
Whether all SAEs intimated to the EC (Yes/No)	
No of AE's reported (Total number, type and outcome)	
Protocol deviations/violations (Number and nature)	
Whether all PD's intimated to the EC (Yes/No)	
Date of study close out	
Conclusion	
Signature of PI Date:	

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054. * ETHICS COMMITTEE *

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Review of Serious Adverse Event

SOP Number	EC SOP 08/V 11
Effective Date	28 May 2019
No of pages	01 to 06
Superseded Version Number & Date	V 10 & 17 Dec 2017

Author:

Name and position in the EC	Signature with date
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Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The purpose of this SOP is to describe the process of the reporting and review of Serious Adverse Events (SAEs) for a study approved by the EC.

2. Scope

This SOP applies to EC review of SAEs reported, both onsite and offsite, including follow up reports submitted by investigators.

3. Responsibility

The primary responsibility of the EC is to review and address the SAE and unexpected events involving risks to research participants. In addition, as per regulation the Committee is authorized to offer mediation under appropriate circumstances as per regulation.

The EC Member Secretary/ Secretary is responsible for receiving the complete SAE / unexpected events reports and directing them to EC for detailed review. Following the SAE are discussed in the subsequent EC meeting or an emergency meeting can be called if required.

4. Detailed Procedure

- At each meeting, Member Secretary/ Basic Medical Scientist/ Pharmacologist will present the data obtained on at site SAE's and on SAE's reported from other centers, for ongoing clinical trials at site to the Committee, and the investigator may be requested to be present for discussion if considered necessary by the EC.

4.1. On Site SAE's

- When a participant who is participating in a research study experiences an unexpected or serious adverse event, the PI must promptly report the incident to the EC with in 24hrs of the occurrence of the event (as per New Drugs and Clinical Trials, 2019), which will be received by Member Secretary/ Secretary, EC who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 11. The report will be forwarded to the Basic Medical Scientist/ Pharmacologist who may call upon the Principal Investigators, if required to explain the causal assessment for the SAE according to him in the next scheduled EC meeting.
- If the research study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must then notify the regulatory authorities within a designated time period.
- Within Fourteen days of the knowledge of occurrence of the SAE of Death/ Fourteen days of the reporting of SAE, the PI must submit a detailed written post analysis report of the serious adverse event or reaction to the Head of the Institution, EC and sponsors in the specified format (as per New Drugs and Clinical Trials, 2019).
- The Secretary, EC will include the SAE, at the next convened full board EC meeting.
- Basic Medical Scientist/ Pharmacologist who has reviewed the SAE in detail before the EC meeting will present a brief summary of onsite reported SAE's to all the members in full board meeting. If thought necessary, the EC may request the PI to be present at that meeting or a subsequent meeting to explain the causal assessment according to him.

- Depending upon the complexity of the issue(s) involved, the Chairman/ Member Secretary will invite one or more experts/ Independent consultant whose opinion would be valuable. These consultant could participate after they agree to the confidentiality clause and abide by the SOP of EC.
- After the SAE of death/SAE other than Death has been reviewed by EC, a detailed remarks on causal relation, compensation, risk benefits assessment etc. will be documented in the minutes and conveyed to the regulatory authorities within a period of Thirty days of receiving the report of the SAE of death/SAE other than Death from investigators as per regulatory guidelines (AX 01/V 01- EC SOP 08/V 10).
- If the EC is unable to take a final decision on causality assessment and compensation requirement and need additional time for review of the SAE, then an initial EC opinion letter will be sent to the regulatory authority clearing describing the reason for requirement of addition time and after complete due analysis the final opinion on causality assessment and compensation will be sent to regulatory authority.
- A copy of letter sent to regulatory authority will be given to PI for necessary action, if any and also a copy will be maintained in EC records. The EC will instruct the PI to forward follow-up reports of the SAE to the EC.
- Under certain circumstance, to meet the regulatory timeline of giving EC opinion, the SAE may be discussed by a Sub-Committee of Ethics Committee constituted by the Chairman consisting of at least 5 Committee member and decision will be documented or the details of the SAE may be circulated to all the Ethics Committee members, the opinion will be sought verbally and the final decision will be documented and approved by the Chairman, which will be forwarded to the regulatory authority.
- The sponsor whether a pharmaceutical company, a government, or an institution, should agree, before the research begins, in the trial agreement to provide compensation for any physical or psychological injury or provide insurance coverage for an unforeseen injury, as per applicable guideline.
- Any noncompliance observed with respect to applicable regulation of compensation for injury will be brought to the notice of the EC and necessary action will be taken by the Committee on case to case basis.
- All SAE compensation has to be notified by PI to the EC.

4.2. Off Site SAE's

- For industry sponsored research trials of drugs or devices, sponsors are required to inform investigators of Serious Adverse Events or reactions that occur at other sites.
- When PI's are informed of the serious adverse events in sponsor safety memos and other correspondence, the PI must review the Serious Adverse Event report and then notify the EC. This should be done as promptly as possible after receipt of the report from the sponsor.
- The CIOMS and other study related notification for each study will be received by Member Secretary/ Secretary, EC who will verify the completeness of the report and follow the steps as mentioned in sectionn4.2 of EC SOP 03/V 11. The report will be forwarded to the Basic Medical Scientist/ Pharmacologist for review of reported causality with study, to generate the external

(non-MSRMCH) SAE report data base to monitor for trends and any such trend/ findings will be brought to the notice of the Committee. He/she will present a brief summary of all external reported initial Death's received by the EC since previous meeting at the next convened meeting.

- If thought necessary, the EC may request the PI to be present at that meeting or a subsequent meeting to review the risk-benefit ratio in the light of the new information based on these reports.
- The compiled SAE data reported from other sites for studies in which M S Ramaiah Medical College and Hospitals (MSRMCH) is a participating center, must be submitted to the Secretary, EC for inclusion in the offsite SAE database.

4.3. Actions to be taken by EC

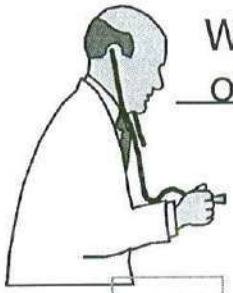
- If a trend is observed in SAE's by PI, such a trend can be reported by EC Member Secretary/Member, action on such reports will be taken by the EC.
- The Chairman, on basis of the information and comments received from the Members of EC and applying his/ her judgment will direct the PI to any one or combination of actions listed below, but are not limited to.
  - Terminate the study.
  - Suspending enrolment of new research participants till further review by the EC.
  - Suspend enrolment of new research participants.
  - Suspending some or all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the EC.
  - Suspend the study till amendments requested for by the EC are accepted.
  - Request additional details.
  - Request further follow up information.
  - Direct the PI to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary.
  - Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment;
  - Any other action.
- The Secretary, EC will send a formal letter to the investigator/s with instructions for specific actions as per the EC decision.

References

- EC SOP- EC SOP 03/V 11- Application Procedures
- New Drugs and Clinical Trials Rules, 2019. G.S.R.227(E) dated 19 Mar 2019.

AX 01- EC SOP 08/V 11

Procedure for SAE Reporting and Compensation



Within 24 hrs. of occurrence

Notify to Sponsor/Representative, DCGI, EC

Pays compensation within 30 days of receipt of order

Head of Institution

INV

Sponsor

Submit the report after due analysis within 14 days

EC

DCGI

Submit the report along with comment on compensation after due analysis within 30 days of receiving the report

In case of Death Licensing Authority shall forward report to Chairman of Expert Committee

Pass order with respect to quantum of compensation within 90 days of receipt of report of SAE.

Expert Committee shall submit the report on causality & quantum of compensation within 60 days from the receipt of report of SAE of death.

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Review of Protocol Deviation/Non-Compliance/ Violation/ Negligence

SOP Number	EC SOP 09/V 11
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Author:

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Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

To provide instructions for taking action and maintaining records when investigators/ trial sites fail to follow/ comply the procedures written in the approved protocol and national / international guidelines / institutional guidelines or rules or procedures mandated by the EC for the conduct of human research. EC will review and will take appropriate action in "consensus" depending upon the nature and severity of deviation/ non- compliance/ violation.

2. Scope

This SOP applies to all EC approved research studies involving human participants/data.

3. Responsibility

The EC Member Secretary/ Secretary are responsible for receiving deviations /violations and noncompliance reports submitted by the Principal Investigator/others and placing it on the agenda of the meeting. EC members should review and take action on such reports.

4. Definition

- **Protocol Deviation:** Any departure from the protocol without prior EC approval is a protocol deviation. In this context the term protocol includes all the documents approved by EC, procedures and applicable regulations.
- **Major Protocol Deviations/ Protocol Violation:** A deviation that affects safety of subjects or has an impact on the integrity of the study data is regarded as a major protocol deviation or Protocol Violation.
- **Minor Protocol Deviation:** A deviation that does not affect the safety of subjects or the integrity of the study is regarded as a minor protocol deviation. Examples: Study procedure or visit conducted out of timeframe, missed study procedures, participant failure to return diary etc.

In general, non-compliance on the part of the research subject is not considered a protocol deviation. For e.g., if a research subject misses a study visit or comes outside the visit window. However, if the non-compliance is widespread the research team should consider strategies to improve compliance. For e.g., if several research subjects miss their appointments, the research team might institute a system to remind subjects about their upcoming appointment by calling them a day or two before the appointment to confirm.

5. Detailed Procedure

5.1. Detection of Protocol deviation/ violation

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below):

- Protocol deviation / non- compliance / violation may be reported by the PI/ study site/ sponsor/ Contract-Research Organization to the EC.
- The EC members performing monitoring of the project at trial site may detect Protocol Deviation/Non-Compliance/Violation, if the project is not conducted as per protocol/ national/

international regulations, or while scrutinizing annual / periodic status reports / SAE reports or other communication received from the Investigator / trial site / sponsor / CRO.

- Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.

5.2. Receipt of protocol deviation / violation report

- If a Protocol deviation / non-compliance / violation has been observed, the PI will ensure that the issue as well as the details of non-compliance are submitted to the EC in writing within 7 days of study team becoming aware (AX 01- EC SOP 09/V 11).
- The Protocol Deviation report will be received by Member Secretary/ Secretary who will verify the completeness of the report and follow the steps as mentioned in section 4.2 of EC SOP 03/V 11.
- The report will be forwarded to Member Secretary/ Basic Medical Scientist and will be scrutinized for gravity and implications. Additional information or material may be requested in order to appropriately evaluate the event.
- The Protocol Deviation report will be placed on the agenda of the forthcoming EC meeting for discussion and necessary opinion or suggestions.

5.3. Actions to be taken

- The committee will review the information available and take a decision depending on the seriousness of the deviation/violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded.
- The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.
- The EC decision will be communicated to PI in writing by the Member Secretary.
- The decision/actions taken by EC could include one or more of the following (but not limited to those listed below):
  - ✓ Note the acknowledgement of the receipt and no further information or action required.
  - ✓ Inform the PI that EC has noted the violation / noncompliance / deviation and inform the PI to ensure that deviations / noncompliance / violations do not occur in future and follow EC recommendations.
  - ✓ Enlist measures that the PI would undertake to ensure that deviations / noncompliance /violations do not occur in future.
  - ✓ Reprimand the PI.
  - ✓ Call for additional information or suspend the study till additional information is made available and is scrutinized.
  - ✓ Suspend the study till recommendations made by the EC are implemented by the PI and found to be satisfactory by the EC.
  - ✓ Suspend the study for a fixed duration of time.
  - ✓ Keep other research proposals from the PI/ Co-PI under abeyance.
  - ✓ Review and / or inspect other studies undertaken by PI/Co-PI.

5.4. Records and follow up to be kept by EC Secretary

- The Secretariat will keep a copy of the notification letter in the respective Study EC notification file.

References

- EC SOP- EC SOP 03/V 11- Continuing Review of Study Protocols

AX 01- EC SOP 09/V 11

Protocol Deviation Report Format

(The details to be provided by PI)	
Protocol No. and Title:	
Principal Investigator:	
Subject Number and initials	
Age/ Sex	
Date of Occurrence of Protocol deviations/violations	
Classify the lapse (Tick the appropriate box) :	☐Consenting ☐Enrollment ☐Laboratory assessment ☐Investigational Product ☐Safety Reporting ☐Source documentation ☐Staff ☐Participant non-compliance ☐Others (Please specify):
Complete Details of Protocol deviations/ violations	
Categorization of Protocol deviations/ violations as per PI/Co-I/Sub-I (Major/Minor)	
Action taken by PI/Co-I/Sub-I	
Impact on (if any): - Trial participant - Quality of data	
Total number of similar deviations /violations/ occurred for the same trial:	
Total number of deviations /violations/ reported till date on the study	
No. of participants Screened/ Randomized	
Protocol deviations/ violations identified by (Principal Investigator / study team or Sponsor / Monitor or EC)	
Signature of PI Date:	

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Review of requests & complaints from participants / patients and other stake holders

SOP Number	EC SOP 10/V 11
Effective Date	28 May 2019
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Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

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Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	K Sr 28/5/19

Table of Contents:

1. Purpose

The EC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the EC as its primary responsibility. Informed Consent documents reviewed by the EC inform the study participant that queries regarding their rights as a participant in the study may be addressed to the EC, Member Secretary/ Chairman, and the EC address and phone number are provided. This SOP provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

2. Scope

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the EC.

3. Responsibility

It is the responsibility of the EC Member Secretary to provide the required information to the research participants/ research participant's representatives/patient, in the case of queries received. It is the responsibility of the Member Secretary/Chairman to initiate a process of giving information to the participants or identifying and addressing any injustice that has occurred, if complaints are received from research participants or other stake holders like participants relative.

4. Detailed Procedure

- The contact details of the Ethics Committee will be available to the subject in the ICF and will also be made available at the department of Clinical Research, the subject waiting area and the consenting room.
- During the routine or for cause monitoring by the members, patients will be interviewed and will enquire about issues/request/ complaints/grievance, if any
- The EC member/ administrative staff who receive an enquiry or request from research participant/ patient will document the same in the Request Record form (AX 01- EC SOP 10/V 11) and will inform the Chairman and Member Secretary about the query/complaint received from the research participant.
- The Member Secretary will provide information required by the research participant or representative in case of an enquiry or request.
- In case of complaint received from a research participant, the Chairman/ Member Secretary initiates a process to identify and address any injustice that may have occurred.
- The Chairman will direct the Member Secretary to consider the matter for discussion at a full board meeting or to call an emergency meeting of two or more EC members for discussion or to appoint a Sub- Committee of two or more EC members for enquiry in order to resolve the matter.
- The Chairman / Member Secretary / designated EC members will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.
- The EC will insist on factual details to determine reality between truth and individual perception.

- The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Member Secretary.
- The EC members are informed about the action taken and the outcomes in the forthcoming EC meeting.
- The Request Record form is filed in the "Request Response" file by the Member Secretary / Secretary, EC. A copy of the same is kept in the study file. The file is stored in a secured place.
- EC may seek feedback from selected individuals who took part in the above activity and the same will be documented.
- The information including any action taken or follow-up and final decision will be recorded in the form AX 01- EC SOP 10/V 11 and the form is signed and dated.

AX 01- EC SOP 10/V 11

Form For Requests & Complaints from participants / patients and other stake holders

Date Received:	
Received by :	
Request/ Complaint received through:	☐Telephone call No ☐Fax No ☐letter / Date ☐E-mail / Date ☐Walk-in: Date / Time ☐Other, specify
Participant's Name:	
Participant's Contact Address & Phone No:	
Title of the Participating Study	
Start date of participation :	
Information Requested/Query/Complaint?	
Request/Query/Complaint done by:	
Relationship with the subject:	
Action taken:	
Outcome:	
Patient Feedback on the Action Taken:	
Date of EC meeting (if applicable):	

Name of the Chairman / Member Secretary : _____

Signature of the Chairman / Member Secretary : _____

Date : _____

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Record keeping and Archiving- Maintenance of Documents of Ethics Committee Activity, Active study files, Archival, Dispose of closed files and retrieval of documents

SOP Number	EC SOP 11/V 11
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Author:

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Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

To provide instructions for preparation and maintenance of study files and other related documents approved by the EC, and storage/archival of closed files and retrieval of documents.

2. Scope

This SOP applies to all active study files, closed files and their related documents that are maintained in the EC office and archival site.

3. Responsibility

It is the responsibility of EC staff to ensure that all study files are prepared, maintained, and kept securely for complete period of the study and for five years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time).

4. Documents pertaining to EC functioning

- The following records will be archived and maintained by the Office of Ethics Committee. Access to this data will only be on a need basis and will be made available for inspection by authorized representatives of regulatory authorities after receiving the request in writing. Care will be taken to maintain security, integrity and confidentiality of this data.
- Ethics Committee related records:
  - Invitation, Acceptance and Appointment letters of each member.
  - Signed and Dated Curriculum Vitae (CV) of all members of EC.
  - Confidentiality and Conflict of Interest form for all EC members.
  - Training records for each EC member.
  - EC SOP training records for EC members.
  - Documentation of resignation/termination of EC members.
  - EC membership roster and Standard operating procedure of the Committee.
  - At every meeting, the members present shall sign the attendance register for the purpose of record keeping.
  - The agenda of all the EC meetings.
  - The minutes of all the EC meetings duly signed by the Chairman.
  - Copy of all existing relevant National and International guidelines on Research Ethics and Laws along with amendments.
  - Copy of all administrative correspondence with members, researchers.
  - List of files in EC Office

5. Active clinical trial files maintenance & archival of closed files

- A Study File (Submission File and Notification File) is the file comprising all essential documents and correspondence related to the Clinical trial/protocol. Study files will be established at the time of initial submission in the EC office.
- One copy of all the documents submitted by the applicant like study protocols along with all enclosed documents will be maintained as per the monthly meeting schedule in the study EC Submission file along with a copy of decision and advice or requirements sent to the applicant and

correspondence with regulatory bodies. All correspondence between Ethics Committee and Principal Investigator/ Study team including Interim/ final study report of the approved projects, Deviation/Violation/ Non-compliance, SAE's, general notifications of clinical trials will be maintained in the EC notification file.

- The study files are assigned serial no. as identifiers and a list of the same along with the details of the assigned reviewer will be maintained for easy tracking.
- All active files are kept in a secured cupboards with controlled access. Only authorized individuals' i.e. EC Secretary/Member Secretary will have access to the files.
- All closed study files are archived and arranged in the Cupboards in Archival room with controlled access. EC Secretary will arrange the closed project files to be archived once the completion/status reports are reviewed by the EC. The completed/closed project files are clearly labeled and stored in the archival room. Only the EC and the regulatory authorities would have access to these files.
- All EC documents pertinent to clinical trials are maintained in EC office for complete period of the study and will be archived for a minimum period of 5 years after completion of the trial (hard copies and soft copies if any) as per applicable rules and regulations and care will be taken to maintain the confidentiality.
- For academic studies one copy of documents submitted during initials submission will be maintained in EC common file however copy of all the follow up activities post approval for academic studies will be maintained by the Department of Research and Patency (DRP), and will be available for review on request.

6. Disposal of closed files and copies of protocols and documents submitted for EC review

- All closed study files after completion of archival period, will be shredded and disposed off. A log book of disposed documents will be maintained, providing details of documents being disposed off (AX 02- EC SOP 11/V 11).
- All the copies of research projects and documents submitted for EC review will be shredded off by the authorized EC personnel after the EC meeting without any notification to PI and no log will be maintained for this.

7. Accessibility / Retrieval

- The EC study file for clinical trials will be made available to EC members and relevant statutory authority upon request. These files will also be made available for inspection and copying by authorized representatives of regulatory authorities or Investigator after receiving the request in writing (AX 01- EC SOP 11/V 11).
- The EC Secretary will furnish a copy of the required document within a week with EC Member Secretary's consent.
- For administrative purposes, the EC Secretary/ Member Secretary can retrieve archived file(s) without requiring the Chairman's approval.

AX 01- EC SOP 11/V 11

Policy for Record retrieval for access to information for inspection and audit and continual protection of trial subjects, post-trial closure with prior permission in writing

Document Request Form

Project No.:	Project Title :
Name of PI:	Requested by:
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Permission of Member Secretary, EC YES/NO Signature of Member Secretary, EC	

AX 02- EC SOP 11/V 11

Format of Dispose off Register for Closed out Clinical Trials

Project No and Title	PI	No. of files	EC approval Date	Study Initiation Date	Study Closure Date	Date documents are disposed off	Name &Sign of Authorized Individual

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Site Monitoring

SOP Number	EC SOP 12/V 11
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Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

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Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select a site for monitoring and how the site will be monitored.

2. Scope

This SOP applies to all EC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the EC.

3. Responsibility

It is the responsibility of the Full Board or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated EC member(s) to perform on-site inspection of selected study, EC has approved.

4. Detailed Procedure

- As a message of abundant precaution that a random monitoring of research projects may be conducted from time-to-time by the EC member to internally evaluate/ inspect/ monitor/ audit working of the approved proposals, to assess effectiveness, efficiency and observance of the norms by the PI.
- Passive Monitoring: The EC receives information about research projects like SAE reports, progress reports etc., which is reviewed and the information is used to assess if projects are progressing well devoid of scientific and ethical breaches.
- Active Monitoring: EC members physically visit research project(s) in to assess if projects are being conducted as per approved protocols.

4.1. Selection of study

- The EC member will select during the EC meeting a random study for monitoring depending upon the complexity and duration of the study and assign a team of two or more members for monitoring.
- The assigned members can perform the live monitoring during the regular subject visit or can perform a random inspection of the protocol compliance process made especially in the event of reporting of adverse events or pertaining violations of human rights.
- "For cause" monitoring will be performed at sites for reasons identified by any member of EC, approved by Chairman. For cause monitoring could be initiated, in any of the following conditions:
  - High number of protocol deviations,
  - Large number of studies carried out by the PI,
  - Large number of Serious Adverse Events (SAE) reports,
  - High recruitment rate,
  - Non-compliance or suspicious conduct and/or complaints for the trials approved by the ethics committee,
  - Complaints received from participants or any other person,
  - Frequent failure to submit the required documents
  - Any other cause as decided by EC.

4.2. Before the visit

- If the study is identified for routine random/ for cause monitoring, the assigned EC member will perform the task of monitoring.
- For routine monitoring the Secretary, EC will inform the PI/study team verbally and the date/time of monitoring visit will be decided based on mutual convenience of the EC member and PI.
- The EC member will also:
  - ✓ Contact the study team to notify them that they will be visiting them.
  - ✓ At that time, study team will coordinate the time for the site evaluation visit.
  - ✓ The EC member may review the EC project files for the study and make appropriate notes.
  - ✓ The EC member can also meet the participant during their regular visit and note the observation.

4.3. During the visit

- Researchers will be expected to provide all the documents as requested by the EC member and/or designee for review. The PI and his/her research team shall have to cooperate with EC member designated for the same.
- The EC member will
  - ✓ Review the informed consent document to make sure that the site is using the most recent version and will also ensure if continuity of Informed Consent Process is being maintained.
  - ✓ Review randomly the subject files to ensure that subjects are signing the correct informed consent and are continuously being updated with safety information.
  - ✓ Observe the informed consent process, if possible.
  - ✓ Review the study participants who have been recruited to ensure that equitable selection of subject is done, with special attention to vulnerable and high risk subjects.
  - ✓ Ensure that subject's right, safety and wellbeing are protected.
  - ✓ Ensure the subject being informed and comprehend about risk-benefits and ongoing safety information.
  - ✓ Review the project files for the study to ensure that documentation is filed appropriately.
  - ✓ Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.
  - ✓ Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.
  - ✓ Verifying that the investigator is enrolling only eligible subjects.
  - ✓ Checking the accuracy and completeness of the source documents.
  - ✓ Determining whether all adverse events (AE's) and SAE's are appropriately reported within the time periods as required by ICH-GCP, Indian GCP, EC and the applicable regulatory requirement(s).
  - ✓ Monitor any noncompliance in compensation for injury to the subject, as per New Drugs and Clinical Trials Rules, 2019, the EC, and the applicable regulatory requirement(s).
  - ✓ Collect views/feedback of the study participants, if possible.
  - ✓ Prepare the Site Monitoring Visit Report (AX 01- EC SOP 12/V 11) and write the comments.

4.4. After the visit

- The EC member will complete the report describing the findings of the monitoring visit with suggestions for improvement for site conduct of clinical study and during the Full Board meeting present the report (AX 01- EC SOP 12/V 11).
- The Secretary, EC will place the report in the correct files.
- After monitoring (routine or for cause monitoring), full board recommendations for the finding will be taken. The decision of the committee whether no action required and continuation of the project or if the committee recommends corrective action for improvement in the process/change the study / premature termination, will be communicated to the PI in writing and will be documented in the Minutes of the meeting.

AX 01- EC SOP 12/V 11

Site Monitoring Visit Report Format

Date of the Visit:	
Protocol No and Title:	
Principal Investigators:	
Department	
Institute:	
Sponsor/CRO:	
Date of EC Approval:	
Date of Initiation:	
Duration of study	
Reason for monitoring	☐Routine ☐For cause monitoring (state reason): - protocol deviations, - Large number of studies carried out by the PI, - SAE reports, - High recruitment rate, - Non-compliance or suspicious conduct - Any complaints related to research - Frequent failure to submit the required documents - Other _____
Project status	☐Ongoing ☐Recruitment completed ☐Follow ups ☐Completed ☐Suspended ☐Terminated
Recruitment status	➢ Total participant approved to be recruited_____ ➢ Total number of participant screened_____ ➢ Total number of participant randomized_____ ➢ Screen failure_____ ➢ Active_____ ➢ Completed_____ ➢ Withdrawn_____ Reason_____ ➢ Discontinued_____ Reason_____

Are Informed Consents of recent version used? ☐Yes ☐No	Comment:
Is it approved by the EC? ☐Yes ☐No	Comment:
Whether consent has been taken from all participants? ☐Yes ☐No	Comment:
Whether appropriate consent form has been signed and dated in ink by participant or LAR (if required, witness) and PI/ Person taking consent? ☐Yes ☐No	Comment:
Whether appropriate vernacular consent have been taken? ☐Yes ☐No	Comment:
Whether adequacy of Informed Consent Process was checked? ☐Yes ☐No	Comment:
Whether adequacy of Audio Video recording of consent process was checked (whenever applicable)? ☐Yes ☐No ☐NA	Comment:
Whether continuity of Informed Consent Process was checked (Re-consenting, if applicable)? ☐Yes ☐No ☐NA	Comment:
Is the subject being informed and comprehend about risk-benefits and ongoing safety information (CIOMS)? ☐Yes ☐No	Comment:

☐NA	
Whether Equitable selection of subjects done (in term of Socioeconomic Status, Gender, Age distribution)? ☐Yes ☐No	Comment:
Eligibility of randomized subject was found to be appropriate? ☐Yes ☐No	Comment:
Is travel reimbursement paid to the subjects? ☐Yes ☐No	Comment:
How well are participants protected? ☐Good ☐Fair ☐Not good	Comment:
Interviewed the subject (Telephonic/ In person)? ☐Yes ☐No	Comment:
Are Protocols of recent approved version used? ☐Yes ☐No	Comment:
Any AE/SAE reported? ☐Yes ☐No ☐NA	Comment:
Number of AEs reported?	Comment:
Number of SAEs reported?	Comment:
Were the SAEs informed to EC within 24 hrs? ☐Yes ☐No ☐NA	Comment:
Were the SAEs Post analysis report sent to EC within 14 days? ☐Yes ☐No ☐NA	Comment:
Was the SAE medical management taken care by sponsor?	Comment:

☐Yes ☐No ☐NA	
Was the SAE compensation given, if recommended by DCGI? ☐Yes ☐No ☐NA	Comment:
Are protocol non-compliance / violation noted? ☐Yes ☐No ☐NA	Comment:
Are protocol non-compliance / violation notified to EC? ☐Yes ☐No ☐NA	Comment:
No of participants reviewed during the visit	
Duration of visit: .....hours	Starting from: Finish:
Any outstanding tasks or results of visit? Give details: ☐Yes ☐No	Comment:
Opportunity for improvement for site conduct of clinical trials:	
Any additional Comments: ☐Yes ☐No	Comment:
Name of EC member: Sign & Date:	
Name of study team member (PI/Co-I): Sign & Date:	

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Studies involving Vulnerable Population

SOP Number	EC SOP 13/V 11
Effective Date	28 May 2019
No of pages	01 to 12
Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	28/5/19

Table of Contents:

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations.

2. Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable population submitted to the EC.

3. Responsibility

- EC Chairman/ Member Secretary is responsible for ensuring that EC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for review of such research, and for securing appropriate consulting expertise as needed for selected reviews.
- EC member is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

4. Definition

- Vulnerable: Individuals whose willingness to volunteer in a Clinical Trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate (ICH GCP 1.61).
- Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

5. Mandate

Gazette notification dated 31st July 2015, [G.S.R. 611(E)] has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of new chemical entity/ new molecular entity.[http://www.ferci.org/wpcontent/uploads/2014/07/Gazette-Notification-31-July-2015-AV-consent.pdf].

6. Detailed Procedure

- Special care is taken for reviewing these protocols to protect safety and wellbeing of such population. Subject experts from the relevant faculty and representative of vulnerable population that is to be researched will be invited as and when necessary while reviewing such protocols.
- The protocol should be reviewed in full board meeting. Additionally, the protocol should be reviewed to assess if the following points are addressed:

✓ Can the research be performed in any other non-vulnerable participants?
✓ Is there justification to use vulnerable population?
✓ Do the benefits justify the risks?
✓ Are the participants selected equitably?

- ✓ Have the measures to protect Autonomy of the vulnerable population been described?
- ✓ EC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.
- Vulnerable population will be specially taken care as follows:
- ✓ Research on genetics should not lead to **racial inequalities.**
- ✓ Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them.
- ✓ Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented.
- ✓ Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, and employees, service personnel, minority community etc. who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.
- ✓ In studies involving minority population, a consultant from that community may be invited as representative to give opinion.
- ✓ **Children:** Before undertaking research/trial in children the investigator must ensure that:
  - Children will not be involved in research that could be carried out equally well with adults.
  - The purpose of the research is to obtain knowledge relevant to health needs of children.
  - For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults.
  - The assent of the child should be obtained.
  - The child's refusal to participate in research must always be respected.
- ✓ **Pregnant or nursing women**: Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation.
- ✓ **Research related to termination of pregnancy:** Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for research as per The Medical Termination of Pregnancy Act, GOI, 1971.
- ✓ **Research related to pre-natal diagnostic techniques:** In pregnant women such research should be limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the fetus.
- Wherever necessary the EC approval should state that if in future the vulnerability status of the participants changes, for e.g. unconscious patient gaining consciousness, the participant will be re-consented.

Reference:

- Gazette notification dated 31st July 2015, [G.S.R. 611(E)]

NOTE: The following annexures apply to some sections of vulnerable participants. These checklists should be filled in by principal investigator and will be reviewed by EC members.

AX 01- EC SOP 13/V 11

Checklist: Requirements for Research Involving Children

Institute		Date :		
Protocol Number & Title:				
Principal Investigator/ Department				
Co – investigator(s)/ Department				
Sponsor/CRO				
Sl. No.		**Yes**	**No**	**NA**
1	Does the research pose greater than minimal risk to children?			
	If yes: Are convincing scientific and ethical justifications given?			
	If yes: Are adequate safeguards in place to minimize these risks?			
2	Does the study involve healthy children?			
	a) If yes: Is the inclusion of healthy children justified?			
3	Are the studies conducted on animals and adults appropriate and justified?			
	a) If No: Is the lack of studies conducted on animals and adults justified?			
4	Will older children be enrolled before younger ones?			
5	Is permission of both parents necessary?			
	a) If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
	b) If Yes: Are the conditions acceptable?			
6	Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
7	Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
8	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			

9	Are there special problems that call for the presence of a monitor or EC member during consent procedures?			
10	Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
11	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
12	Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)			
13	If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
14	Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

Signature of Principal Investigator: _____ **Date** _____

EC Office use only	
Comments of Assigned Reviewer:	
Recommended Action	☐ Approval ☐ Modifications ☐ Disapproval Reasons for disapproval: ☐ Deferred, if major clarifications are required before a decision can be made.
Assigned Reviewer Name	
Assigned Reviewer Signature and Date	

AX 02- EC SOP 13/V 11

Checklist: Requirements for Research Involving Pregnant Women and Fetuses

Institute		Date :		
Protocol Number & Title:				
Principal Investigator/ Department				
Co – investigator(s)/ Department				
Sponsor/CRO				
Sl no	**When research involves pregnant women or fetuses**	**Yes**	**No**	**NA**
1	Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
2	Is the risk to the fetus not greater than minimal, or any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
3	Any risk that is the least possible for achieving the objectives of the research?			
4	Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived?			
5	Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?			
6	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7	Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?			
8	Do individuals engaged in the research have a part in determining the viability of a fetus?			

If the response to any of the above is **NO**, the research should not be approved by the EC

Sl no	**When research involves neonate after delivery**	**Yes**	**No**	**NA**
1	Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates?			

2	Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate?			
3	Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?			
4	Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy?			
A. Fetuses of uncertain viability				
1	Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research? OR The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means. Will there be a risk to the fetus from the research?			
2	Is the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative obtained			
B. Nonviable fetuses				
1	Will vital functions of the neonate be artificially maintained?			
2	Is there any risk to the neonate resulting from the research?			
3	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
4	The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)			

If the response to any of above is **NO**, the research should not be approved by the EC.

This type of research can be conducted only after the EC finds that

a. The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses.
b. The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Signature of Principal Investigator: _____ Date _____

EC Office use only	
Comments of Assigned Reviewer:	
Recommended Action	☐ Approval ☐ Modifications ☐ Disapproval Reasons for disapproval: ☐ Deferred, if major clarifications are required before a decision can be made.
Assigned Reviewer Name	
Assigned Reviewer Signature and Date	

AX 03- EC SOP 13/V 11

Checklist- Research Involving Cognitively Impaired Adults

Institute		Date :	
Protocol Number & Title:			
Principal Investigator/ Department			
Co – investigator(s)/ Department			
Sponsor/CRO			
Sl no	**1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant** (All items must be "Yes")	**Yes**	**No**
1	Is the recruitment of participants justified considering the rationale and objectives of the study?		
2	The risk is justified by the anticipated benefit to the participants.		
3	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.		
4	Will the participants be withdrawn if they appear to be unduly distressed?		
5	The proposed plan for the assessment of the capacity to consent is adequate.		
6	The proposed plan for the assessment of the capacity to consent is adequate.		
7	Consent will be taken from participants capable of being consulted.		
8	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?		

Sl no	2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes"	Yes	No
1	Is the recruitment of participants justified considering the rationale and objectives of the study?		
2	Are the foreseeable risks to the participants low?		
3	Is the negative impact on the participant's well-being minimized and low?		

4	Will the participants be particularly closely monitored?		
5	Will the participants be withdrawn if they appear to be unduly distressed?		
6	The proposed plan for the assessment of the capacity to consent is adequate.		
7	Consent will be taken from participants capable of being consulted.		
8	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?		

Signature of Principal Investigator: _____ **Date** _____

EC Office use only	
Comments of Assigned Reviewer:	
Recommended Action	☐ Approval ☐ Modifications ☐ Disapproval Reasons for disapproval: ☐ Deferred, if major clarifications are required before a decision can be made.
Assigned Reviewer Name	
Assigned Reviewer Signature and Date	

AX 04- EC SOP 13/V 11

Checklist: Research Involving Students, Employees or Residents

Institute	Date :
Protocol Number & Title:	
Principal Investigator/ Department	
Co – investigator(s)/ Department	
Sponsor/CRO	

Sl no	Participants who are students, employees or residents require special considerations.	Yes	No
1	Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?		
2	Have the risks to participants been minimized?		
3	Have participants been assured that participation is voluntary (no signs of coercion)?		
4	Have participants been assured that privacy and confidentiality will be protected?		

Answers to all the above points should be **YES** for approval

Signature of Principal Investigator: _____ **Date** _____

EC Office use only	
Comments of Assigned Reviewer:	
Recommended Action	☐ Approval ☐ Modifications ☐ Disapproval Reasons for disapproval: ☐ Deferred, if major clarifications are required before a decision can be made.
Assigned Reviewer Name	
Assigned Reviewer Signature and Date	

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

Ethics Committee, M S Ramaiah Medical College and Hospitals

Title: Ethics Committee: Fee Structure For Protocol Review

SOP Number	EC SOP 14/V 11
Effective Date	28 May 2019
No of pages	01 to 05
Superseded Version Number & Date	V 10 & 17 Nov 2017

Author:

Name and position in the EC	Signature with date
Dr. Reetu Singh (Secretary- EC)	Reetu Singh 28/5/2019

Reviewed by:

Name and position in the EC	Signature with date
Dr. Anuradha H. V. (Member Secretary- EC)	Anuradha 28/5/19

Approved by:

Name and position in the EC	Signature with date
Shri. Justice (Retd) K Sreedhar Rao (Chairman- EC)	K Sr 28/5/19

Table of Contents:

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe EC fee which will be charged for review of proposals and details regarding finance.

2. Scope

This SOP covers the finance part of the Ethics committee.

3. Responsibility

It is the responsibility of the EC finance In-charge/ EC Secretary and Member Secretary to keep an account of EC related finance.

4. Fee Payable

- A non-refundable processing fee will be levied on all research proposals that are funded by agencies or organizations with a commercial orientation (pharmaceutical companies, contract research organizations, etc.) for Ethics Committee approval. This processing fee is independent of the eventual decision to accept, revise or reject the proposal.
- Prescribed fee should be remitted along with the application in favor of "Ethical Review Board" in the form of crossed cheque/ DD/ wire transfer.
- This fee is non-negotiable, however under exceptional circumstances, as decided by the Member Secretary/ Chairman in consultation with the other members, a reduction or waiver of this fee may be made.
- This fee is not applicable to proposals that are of academic interest or proposals that are funded by non-commercial sponsors (governmental or Non-governmental funding agency) and can be stipulated or waived off for Investigators initiated or other collaborative projects at the discretion of Ethics Committee.
- "Ethics Committee" is a unit of Gokula Education Foundation (Medical), hence for the purpose of payment of fee, the PAN No. AAATG1779Q belonging to Gokula Education Foundation (Medical) needs to be considered by the Sponsor/CRO.

5. Fee for various type of protocols

- Fees pertinent for review of various types of documents used for clinical research activities being conducted at M. S. Ramaiah Medical College and Hospitals is mentioned below. The processing fees has to be paid before approval of the protocol. Tax will be applicable as per law.

Sl. No.	Type of Documents	Fees (in Rs.)
1	Initial review of the Clinical trial protocol and related study documents	60,000/-
2	Review of Clinical Trial SAE and opining	5,000/-
3	Review of clinical trial protocol and related study document amendment	1000/-
4	Expedited review of clinical trial document	10,000/-

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS BANGALORE-560054. ETHICS COMMITTEE

- Fees pertinent for review of various types of documents used for research activities being conducted at Ramaiah Indic Specialty Ayurveda (RISA) is mentioned below.

Sl. No.	Type of Documents	Fees (in Rs.)
1	Initial review of the clinical trial protocol and related study documents	30,000/-
2	Review of Clinical Trial SAE and opining	5,000/-
3	Review of clinical trial protocol and related study document amendment	1000/-

- Fees pertinent for review of various types of documents for Phase II, III, IV studies, BA/BE studies, registry and observational studies and alternative medicine studies being conducted by CRO or other institutes outside M. S. Ramaiah Medical College and Hospitals is mentioned below. The processing fees will be paid as per MOU with CRO/Other institute. Tax will be applicable as per law.

Sl. No.	Type of Documents	Fees (in Rs.)
1	Initial review of the protocol and related study appendices.	60,000/-
2	Review of protocol amendment/SAE.	5,000/-
3	Ratification of minor amendments to protocol.	5,000/-
4	Review of other non-study related document (e.g. Advertisement, SOP etc.), facility visit and audit of ongoing studies as per regulatory requirement.	N/A
5	Review of minor errata, corrections, minor changes for administrative purposes.	5,000/-
6	Review of change in the basic aspects, like change in study site/s, number of subjects, drug/s or its formulations, study procedures etc.	5,000/-

- For Phase I studies which are being conducted at M. S. Ramaiah Medical College and Hospitals OR other centers the review fee will be Rs 65,000/- (plus applicable taxes).
- Fees pertinent for review of various types of research documents for faculty from Ramaiah Sister Institutes (like Nursing, Pharmacy, IMS etc.) and PhD program for outside university is Rs 500/- per study (plus applicable taxes).
- Fees pertinent for review of faculty collaborative research work with other institute (e.g. IISc, other non-commercial sponsors) is Rs 5000/- per study (plus applicable taxes), at case based discretion of Ethics Committee.
- Fees exemption for:
  - ✓ Under Graduate and Post Graduate academic research and dissertation projects.
  - ✓ All M S Ramaiah Medical College and Hospitals departmental faculty academic research projects.

M.S. RAMAIAH MEDICAL COLLEGE & HOSPITALS * BANGALORE-560054 * ETHICS COMMITTEE *

6. Honorarium Payment

- The CE, GEF (Medical) has directed the administration for the payment of honorarium to the member(s) for investing extra time and intellectual capital in decision making process.
- Members of the EC will be paid a sitting fee, for attendance and participation at each EC meeting.
- The honorarium will be paid to special Invitee's affiliated or not affiliated to the Institution, at the rate decided by Member Secretary.

7. Financial Declaration of EC

- The financial details of the EC in terms of amount received and dispersed will be maintained by Secretary, EC, however the financial accountability and compilation of the same will be done by the In charge person from the accounts department of M S Ramaiah medical college and Hospitals.
- The sitting fees to the EC members will be paid by cheque/online, the details will be mentioned in the attendance register and the members will acknowledge the same.
- Details regarding expenditure with regard to catering and other administrative cost related to the efficient functioning of the Committee will be maintained in the EC accounts file.
- Every month by first week the details of the invoice raised and the payments done and received in the previous month will be sent to the accounts department and the necessary documentation and service tax payment will be done by the In charge accounts personnel.
- April every year, the Secretary, EC shall prepare an Annual finance Report on the working of the Committee which will include the total payments received and spent for that financial year and will be filed in the EC accounts file.
- The EC account is an audited account and transparency will be maintained with respect to financial activities and functioning.