Institutional Ethics Committee
B. J. Medical College & Civil Hospital, Ahmedabad

Standard Operating Procedure (SOP)

Version No. : 05

Release Date: 3rd June, 2015

Name of the Ethics Committee	**Institutional Ethics Committee, B. J. Medical College & Civil Hospital Ahmedabad**
Registration Number	**ECR/72/Inst/GJ/2013 , Office of the Drug Controller General (India)**
Address of the Ethics Committee	**Office of the Medical Superintendent Civil Hospital, Ahmedabad-380016**
Frequency of Ethics Committee Meeting	**Every month or as and when required (depends upon the proposals submitted), and as decided by Member Secretary and Member-Coordinator**
Lead time required by the Ethics Committee before which they discuss documents submitted to them	**4 weeks**
Contact details of Ethics Committee Member Coordinator	**Dr. Mira K. Desai, M.D. (Pharmacologist) Professor & Head, Department of Pharmacology B. J. Medical college, Ahmedabad- 380016**

Introduction:

The need for evaluation of research has been emphasized under the general principles pertaining to precaution and risk minimization. It is mandatory that all proposals on biomedical research involving human subjects should be cleared by an appropriately constituted Independent Ethics Committee (IEC) to safeguard the welfare and the rights of the participants. The Ethics Committee is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also has a continuing responsibility of regular monitoring for the compliance of the ethics of the approved proposals till completion. Such ongoing reviews will be in accordance with the Declaration of Helsinki and all the National and International guidelines for biomedical research on human subjects.

Objectives:

The objective of this standard operating procedure is to contribute to ensure the effective functioning of the Institutional Ethics Committee of B. J. Medical College & Civil Hospital, Ahmedabad so as to achieve a competent and consistent ethical review mechanism for health and biomedical research proposals dealt by the committee as prescribed by the Ethical Guidelines for Biomedical Research on Human Subjects, Indian Council of Medical Research (ICMR). The Ethics Committee of B. J. Medical College & Civil Hospital Ahmedabad is an Institutional Ethics Committee (IEC).

Role:

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants. The goal of research, however important would never be permitted to override the health and well being of the research subjects. Independence and competence will be the two hall-marks of the Ethics Committee.

The IEC will take care of all cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process,care and protection of research participants, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations whenever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after the completion of the study through appropriate well documented procedures. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

Title: Authority and Procedure for IEC Constitution

SOP 01/V5 dated, 3rd June, 2015

The institutional Head, Medical Superintendent, Civil Hospital, Ahmedabad will nominate the IEC by appointment of scientific and non-scientific members. The appointment of members will be based on qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study. Moreover, competencies, integrity and awareness of local, social and cultural norms will also be considered.

1.1. Composition of IEC:

IEC will be multidisciplinary and multi-sectorial in composition including relevant scientific expertise, balanced age and gender distribution, a social worker and lay person. The Ethics Committee will comprise of 10 members with medical/ non-medical scientific and non-scientific persons including lay person. The minimum of 5 members will be required to compose a quorum.

The composition may be as follows:

- Chairperson: The chairperson of the committee would be from outside the institution to maintain the independence of the committee.
- Member secretary: The member secretary belongs to the same institution
- Member coordinator : The member coordinator belongs to the same institution to conduct business of the committee
- One basic medical scientist preferably pharmacologist
- 4-5 clinicians of the institute
- One legal expert (e.g. lawyer or retired judge)
- One social worker
- One lay person from the community

The current composition of IEC is as follows:

Sr. No.	Name of the Member	Designation and Qualification and Gender	Address, Phone and email
1.	**Dr. R.K. Dikshit** **(Independent of institution)**	**Chairman (M)** **(Scientific)** Pharmacologist MBBS, M.D. (Pharmacology)	Professor & Head, Department of Pharmacology, GCS Medical College, Ahmedabad 380025 ram.dikshit@gcsmc.org, ramdikshit@gmail.com 079-6604 8499(O), 9824164794 (M)
2.	**Dr. M.M. Prabhakar**	**Member Secretary (M)** (Scientific) Clinician Medical Superintendent Professor & Head, Orthopedics MBBS, M.S. (Orthopedics)	Medical Superintendent Civil Hospital, Ahmedabad 380016 drmmprabhakar@gmail.com 09978405057
3.	**Dr. Mira K. Desai**	**Member Coordinator (F)** (Scientific) Pharmacologist Professor & Head, Pharmacology MBBS, M.D. (Pharmacology)	Department Of Pharmacology B. J. Medical College, Ahmedabad 380016 desaimirak@yahoo.co.in 09825057107

4.	**Dr. Asha N. Shah**	**Member, Clinician (F)** (Scientific) Professor & Head, Medicine MBBS, M.D (Medicine)	Department Of Medicine Civil Hospital, Ahmedabad 380016 ashashah55@gmail.com 09327066349
5.	**Dr. G. H. Rathod**	**Member, Clinician (M)** (Scientific) Professor & Head, Surgery MBBS, M.S. (Surgery)	Department Of Surgery Civil Hospital, Ahmedabad- 380016 ghrathod@gmail.com 09428016850
6.	**Dr. M. N. Parikh**	**Member, Clinician (F)** (Scientific) Professor & Head, Psychiatry MBBS, M.D. (Psychiatry)	Department Of Psychiatry Civil Hospital, Ahmedabad- 380016 drminakshiparikh@gmail.com 9825718698
7.	**Dr. M. F. Shaikh**	**Member, Clinician (M)** (Scientific) Professor & Head, Plastic Surgery M.S, M.Ch (Plastic Surgery)	Department Of Plastic Surgery Civil Hospital, Ahmedabad 380016 mfshaikh@hotmail.com 09825159849
8.	**Dr. Amar Vyas**	**Member, (M)** (Non- Scientific) Social worker, Community Medicines M.S W.,Ph.D.	Department of Community Medicines, B J Medical College, Ahmedabad 380016. amar_j_vyas@yahoo.co.in 09825438600
9.	**Mr. P.K. Yadav** **(Independent of institution)**	**Member, Lawyer (M)** (Non- Scientific) B.A., L. L. B. (Advocate)	Kubhaji's wadi, Bhargav road, Meghaninagar, Ahmedabad. pkyadav@yahoo.com 09898626252
10.	**Mr. Hitendra Makwana (Independent of institution)**	**Member , (M)** Lay person (Non- Scientific) S.S.C.	1, Meghdhara Society, Behind Civil Hospital, Ahmedabad- 380016 Hitendra.makwana@yahoo.in 09879503360

1.2 Membership Requirement:

- The Head of the Institute (HOI)(as mentioned above) is responsible for appointing committee members. The Chairperson and the IEC members can suggest names of potential members but the final decision will remain with the HOI.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- The appointment of a member will be for 5 years. The head of the institute may renew the appointment on the basis of the member's contribution.
- Each member should sign a confidentiality form at the beginning of the tenure and maintain absolute confidentiality of all discussion during the meeting.(Annexure-1)
- The member should declare in writing any conflict of interest- financial, professional or otherwise in a project/proposal under consideration at the beginning of the each meeting. (Annexure-2).
- Each member must have been trained in Good Clinical Practice (GCP) at the time of joining the committee. The IEC member Secretary, members, Chairperson will be encouraged to receive continuing training by participation in workshops, conferences, continuing education sessions and/ or retraining programs related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The members may be replaced at the discretion of the Chairperson, Member Secretary, or committee members when a majority vote is obtained. A member may be relieved of membership in case of his/her inability to participate in the meetings on any ground. A member can be replaced in the event of death or long term non availability or any action not commensurate with the responsibilities laid down. A member can tender resignation from the committee with proper reason to do so.

1.3 Quorum Requirement:

The minimum of 5 members are required to compose a quorum. The quorum includes one basic medical scientist, one clinician, one legal expert, one social scientist and one lay person from the community.

1.4 Offices:

The chairperson will conduct all meetings of IEC. The member secretary and member coordinator will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. The member coordinator will prepare the minutes of the meetings and get it approved by the Chairman. The meetings will be conducted at the Office of the Medical Superintendent Civil Hospital, Ahmedabad-380016.

1.5 Responsibility:

The Ethics Committee aims to ensure that all types of human/clinical research protocols being carried out at B. J. Medical College & Civil Hospital, Ahmedabad,

- are sound in scientific design, have statistical validity and conducted according to ICH-GCP Guidelines, DCGI, Schedule Y and Declaration of Helsinki as well as local regulatory requirement,
- do not compromise the safety, rights and well being of the subjects participating in the research study,
- are conducted under an unbiased and unprovoked supervision of the medical person with required experience / expertise,
- include solely, volunteers/patients who have given informed consent for participation in the research study without any provocation whatsoever,
- the committee will review all new research projects and also the ongoing research projects at the intervals appropriate to the degree of risk to the study subjects,
- the committee may call upon subject experts as independent consultants to provide special review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies or represent specific communities, patient groups or special interest groups e.g. cancer patients. The independent consultants should sign the confidentiality form and declare conflict of interest in writing before giving the expert opinion and will not take part in the decision making process of IEC.
- The ethics committee expects from the principal investigator to be informed about the following:

i) A progress report of the clinical study every six months or more frequently, if required.

ii) To communicate all serious and unexpected adverse event (SAE) occurred at the investigative site within twenty four hours (24). And after due analysis, a report along with medical management undertaken to be submitted within fourteen (14) calendar days. For SAEs occurring at the site, the member secretary and member coordinator of IEC should communicate it to the Chairperson within 7 working days and call for emergency meeting (SAE amount to death) or discuss the same in an ordinarily scheduled meeting. The Chairperson, member secretary could invite or solicit opinion in writing one or more independent subject expert, depending upon the complexity of SAE. Timelines for SAE reporting should be followed as per amendment in Rule 122 DAB of the Drugs and Cosmetic Act, 1945 notification by CDSCO.

iii) To inform amendments/ revision/ addendum to any study related documents as well as patient's safety related information.

iv) Any amendment to the protocol from the originally approved protocol with proper justification must also be duly communicated.

v) Any new information that may influence the conduct of the study.

vi) To inform study completion report within one month of completion or discontinuation of the study with reasons.

vii) To submit justification for approval to restart the study, if discontinued earlier.

Title: Procedure for Submission:

SOP 02/V5, dated 3rd June, 2015

The applicant is required to submit an application to the Member-Coordinator in the prescribed form (Annexure 3) accompanied with the proposal with all necessary enclosures duly signed by the principal investigator / co-investigator in three hard copies and 7 soft copies in compact disc minimum fifteen days prior to schedule meeting. This includes the following:

i) A written and signed covering letter from the principal investigator

ii) Final protocol with all amendments with version, date and number.

iii) A case record form (CRF) with version, date and number.

iv) A copy of the patient informed consent form with framework for audiovisual recording and patient information sheet in English and translated in Gujarati and Hindi with appropriate translation certificates with version, date and number.

v) Investigator's Brochure, safety related information and published reports of earlier investigation, if any.

vi) Any other project specific documents.

vii) A copy of the insurance policy with proposed compensation (covering the subjects, investigators and hospital).

viii) A copy of the notification of any payments proposed to be made to study subjects towards reimbursements of incidental/travel expense.

ix) All other relevant documents related to the study protocol including permission from regulatory authorities (DCGI) with version, date and number.

x) Sponsor's undertaking to provide free medical management as long as required and financial compensation in case of serious adverse event or clinical trial related injury or death.

xi) Registration with Clinical Trial Registry of India (CTRI)

xii) Investigator's undertaking to comply with national and international GCP protocols for clinical trials (to be signed and dated).

xiii) Certificate of GCP training by investigator

xiv) Clinical trial agreement tri-partite or four-party(to be signed and dated)

xv) CV of principal investigator along with number of regulatory clinical trials on hand and status of each of them.

xvi) Private sponsor's Rs. 50,000/- deposit in Rogikalyan Samiti (cheque / D.D. in the name of Rogikalyan Samiti, CHA).Original receipt to be attached with the application.

xvii) Other details:

- Patients/volunteers recruitment procedure
- Precise description of methodology of the proposed research work, dosages of drug, planned duration of treatment and details of invasive procedure.
- Details of the funding agency / sponsors and fund allocation for the proposed work.

Title: Meeting Requirements

SOP 03/ V5, dated 3rd June, 2015

3.1 Holding the meeting

i) A non-refundable processing fees of Rs. fifty thousand (Rs.50,000/-) has to be deposited through a crossed bank draft issued in the name of 'Rogi kalyan Samiti, Civil Hospital,

Ahmedabad'. The original receipt of this payment is to be submitted along with the application. **T**his processing fee can be revised from time to time.

ii) The member secretary and member coordinator are responsible for organizing the meetings.

iii) The committee shall meet every month or as and when required based upon the proposals submitted at the Office of the Medical Superintendent, Civil Hospital Ahmedabad. The dates for the meeting shall be decided by the member secretary and member coordinator in consultation with the chairperson.

iv) Advance notice of at least 7 days before each meeting will be sent out by member coordinator to all IEC members along with the agenda and documents/ proposals to be reviewed in the meeting.

v) In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members telephonically and/ or via e-mail.

3.2 Conducting a meeting

i) A quorum of at least 5 members is required to consider/review a protocol and any other study related documents at the meeting. The quorum includes one basic medical scientist preferably pharmacologist, one clinician, one lay person, one social worker and one legal expert.

ii) It is preferable that at least one of the IEC members who is not affiliated to the B. J. Medical College & Civil Hospital, Ahmedabad, one legal expert, one social worker and one clinician remain present during each review meeting

iii) The principal investigator or a suitable representative not below the rank of an Assistant Professor shall make a brief presentation during the meeting and respond to the members' queries, if any. However she/he will not participate in the decision making or the voting process of that study.

iv) A subject expert may be called to the meeting as independent consultant to answer specific queries. The experts may be specialists in ethical or legal aspects, specific disease or methodologies or represent specific communities; patient groups e.g. HIV/AIDS or ethnic minorities. However, he/she will not participate in the decision making or the voting process.

v) The member should declare in writing conflict of interest- financial, professional or otherwise in a project/proposal under consideration at the beginning of the each meeting. (Annexure-2).

vi) If one of the IEC members has his/her own proposal for review, then the member shall not participate in the review, discussion or decision/voting process. The member's non-participation

in the decision/voting process will be recorded in the minutes. The member having actual or potential conflict of interest to any particular proposal submitted for review will abstain from any participation in discussion or recommendations in respect of such proposals. Example of conflict of interest may be, a member being a part of investigator team.

vii) All meetings will be minuted. The minutes will be approved by the Member Secretary and Chairperson and circulated to the members in the next scheduled meeting.

viii) At each IEC meeting, signatures from each member who participated in the meeting will be obtained on the attendance sheet.

Title: Review Elements

SOP 04/ V5, dated 3rd June, 2015

The elements to be reviewed by IEC members (annexure 4) include the following:

4.1 Design and conduct of the study

- The appropriateness of the study design in relation to the objectives of the study and the statistical methodology
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities
- The justification for use of control arms (e.g. placebo, if any)
- Criteria for premature withdrawal of research participants, suspending/terminating research as a whole

4.2 Recruitment of research participants

- The characteristics of the population from which the research participants will be drawn including their age, gender, literacy, economic status and ethnicity
- Inclusion and exclusion criteria for research participants

4.3 Informed consent process

- A full description of the process for obtaining informed consent, including the voluntary, non-coercive recruitment, participation or withdrawal and identification of those responsible for obtaining consent

- Audio visual recording of the informed consent process of each trial subject including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality.
- 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)
- Clear justification for the intention to include in the research individuals who cannot consent along with a full account of the arrangements to obtain their consent.
- The provision for receiving and responding to queries and complaints from research participants or their representatives during the course of research project.
- Information regarding subject's right to claim compensation in case of trial related injury or death.
- Information regarding annual income of the subject, the name and address of the nominee(s) and relation to the subject for making claims in case of trial related injury.
- Translation of the informed consent document in local languages.

4.4 Waiver of informed consent

- A request to waive the written informed consent must be accompanied by a detailed explanation and risk to participants. If the proposed research study presents no more than minimal risk to subjects as per ICMR guidelines, 45CFR 46 e.g. a retrospective review of patient case records to determine the incidence of disease/recurrence of disease, the committee may consider to waive the informed consent. [Minimum risk would be defined as that 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].
- The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of research participants.

4.5 Care and protection of research subjects

- The suitability of the investigator(s)'s qualification and experience for the proposed study
- Any plans to withdraw or withhold standard therapies for the purpose of the research and justification for such action

- The medical care to be provided to research participants during and after the course of the research

4.6 Care and compensation of the research subject in serious adverse events (SAEs) and injury / death during clinical trial

- All serious and unexpected adverse events occurring at the clinical trial site should be communicated with in 24hrs. to IEC. The details of SAE should be submitted in a prescribed form (annexure 5) and the subject should be given free medical management as long as required.
- After due analysis, a detailed report along with medical management undertaken and causality assessment should be submitted in fourteen (14) calendar days.
- The IEC shall review and analyze the SAE report (annexure 6), it may undertake subject expert opinion, if required and forward to licensing authority its recommendations for financial compensation within thirty (30) days of occurrence of ADR.
- An injury occurring to clinical trial subject should be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
- Subject will be liable for financial compensation if the injury or death has occurred because of,
  - i) Adverse effect of investigational product
  - ii) Any clinical procedures involved in the study
  - iii) Violation of approved protocol, scientific misconduct or negligence by sponsors or representative
  - iv) Failure of investigational product to provide intended therapeutic effects
  - v) Use of placebo in a placebo control trial, where the standard care, though available was not provided to the subject as per the clinical trial protocol
  - vi) Adverse effect due to concomitant medication excluding standard care**,** necessitated as part of approved protocol
  - vii) Injury to the child in-utero because of the participation of parent in clinical trial
- If the injury is trial related, subject shall be entitled for financial compensation in addition to free medical management.
- In case of clinical trial related death, nominee(s) would be entitled for financial compensation

4.7 The insurance and indemnity arrangements

4.8 Protection of research participants confidentiality

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

4.9 Research involving vulnerable population

- The IEC exercises particular care to protect the rights, safety and well being of all the vulnerable subjects participating in the study , for example prisoners, staff and medical or nursing students, patients with incurable diseases, unemployed or impoverished persons, ethnic minority groups, homeless persons, nomads, minors or others incapable of giving consent. Members may ensure that subjects and patients invited for research be selected in such a way that the burdens and benefits of the research is equally distributed.
- Economically or socially disadvantaged persons should not be used to benefit those who are better off than them.
- Rights and welfare of mentally challenged and mentally differently abled persons who are incapable of giving informed consent or those with behavioural disorders must be protected. Special justification is required for inviting vulnerable individual to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied. Appropriate proxy consent from the legally acceptable guardian should be taken after the person is well informed.

Title: Decision Making Procedure:

SOP 05/ V5, dated 3rd June, 2015

1. The decision of the committee will be taken by a majority consensus after the quorum requirements are fulfilled to recommend / reject / suggest modifications for a repeat review or advise appropriate modifications. The committee will give its opinion on the proposals as,

- Favourable (approval)
- Unfavourable (reject)

- Modification required before approval (revision)
- No opinion until further clarification or information received by the applicant
- Termination /suspension of any prior approved projects.

Title: Communicating the Decision

SOP 06/ V5, dated 3rd June, 2015

The decision of the IEC will be communicated to the investigator in writing within one week of the meeting

i) The communication of the decision shall include,

- Name and address of the Ethics committee
- The date and place of the IEC meeting
- The name and title of the applicant
- Title of the research proposal reviewed, protocol number, version number, date and or amendment number and date
- Names and number of all documents reviewed e.g. subject information sheet, ICF, applicant's CV etc.
- A clear statement of decision
- Any suggestions / conditions imposed by IEC to the applicant
- In case of conditional decision any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
- Number and name of the members participated
- Signature (dated) of the member coordinator

Title : Expedited Review Process:

SOP 07 / V5, dated 3rd June, 2015

The IEC may undertake expedited review process as per following criteria,

- No or minimal risk to the trial participants
- Re examination of a proposal already examined by the IEC
- Study of minor nature e.g. examination of case records
- All ICMR student projects and postgraduate students dissertation, proposals

- Minor changes or amendments in previously approved project that do not affect the substances of the original protocol and raise major ethical issues.
- The changes involve only logistical or administrative aspects of the trial, e.g. change in monitor, associate and co-investigator, change in telephone no. etc.
- Request for extension for an approved project with no modification of protocol.

i). All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics committee meeting.

ii). All expedited approval will be given in a meeting of Sub-committee of four members nominated by member secretary. Decision taken by the Sub-committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IEC.

Title : Follow up procedures:

SOP 08 / V5, dated 3rd June, 2015

All SAEs and the interventions undertaken should be submitted.

- Protocol deviation, if any, should be informed with adequate justification.
- Any amendment to the protocol should be submitted and approval should be renewed if necessary.
- Any new information related to the study should be communicated.
- Premature termination of the study should be notified with reasons along with summary of the data obtained.
- Progress report of the study to be submitted every 6 months or more frequently, if required.
- Final reports should be submitted at the end of the study.
- Change of investigators/ sites should be informed.

Title: Record Keeping

SOP 09/ V5, dated 3rd June, 2015

Correspondence between the IEC and principal investigator and study team will be retained for a minimum period of 5 (five) years after completion of trial.

- The IEC will retain all the study documents and administrative documents for five years after completion of the research.

Title: Updating IEC members:

SOP 10/ V5, dated 3rd June, 2015

The IEC members will be updated regarding the National Guidelines of clinical research

- IEC members will be encouraged to keep updated of all National and International developments in Biomedical Ethics by orientation courses and training programmes organized by constituted bodies.

Dr. M. M. Prabhakar	Dr. Mira K. Desai	Dr. R.K. Dikshit
(Member Secretary)	(Member Coordinator)	(Chairperson)

Date: 03/06/2015

Amendment in IEC SOP version 5

In the title meeting requirements, the sub point 3.1 relating to holding the meeting, the clause 3.1.1 shall be inserted with the following namely;

3.1.1 Review of Amended protocol/ Protocol related documents

i) The member coordinator/ member secretary/ chairperson will decide whether the proposed protocol amendment(s) need to undergo a full board review, review by designated IEC member or a review by the member coordinator/secretary/chairperson. The member secretary/chairperson can take the decision if the amendment(s) is/are of administrative nature.

ii) The amended protocol/ protocol related document will require full board review for any of the following but not limited to:

- Change in the study design
- Additional treatments or the deletion of treatments.
- Changes in the inclusion/exclusion criteria.
- Change in method of dosage formulation, such as, oral changed to intravenous.
- A significant change in the number of subjects (if the decrease/increase in the number of subjects alter the fundamental characteristics of the study significantly).
- A significant increase or decrease in dose.
- Changes in informed consent form

iii) In case the amended protocol/protocol related document requires full board review, a non-refundable processing fees of Rs. twenty five thousands (Rs. 25,000/-) has to be deposited through a crossed bank draft issued in the name of Rogi Kalyan Samiti Civil Hospital, Ahmedabad. The original receipt of this payment is to be submitted along with the application. This processing fee can be revised from time to time.

iv) In case of an unscheduled or emergency meeting for serious adverse event review and discussion, a non-refundable processing fees of Rs. twenty five thousands (Rs. 25,000/-) has to be deposited through a crossed bank draft issued in the name of Rogi Kalyan Samiti Civil Hospital, Ahmedabad. The original receipt of this payment is to be submitted along with the

initial and final SAE report to the committee. This processing fee can be revised from time to time.

Dr. M. M. Prabhakar (Member Secretary)	Dr. Mira K. Desai (Member Coordinator)	Dr. R.K. Dikshit (Chairperson)

Date: 25/09/2015