OFFICE OF THE ETHICS COMMITTEE (EC)
SMS MEDICAL COLLEGE & ATTACHED HOSPITALS, JAIPUR

STANDARD OPERATING PROCEDURE (SOP)

Composition of the Ethics Committee:

As per order number: 19242-342/MC/GS/2001, dated: 13/06/2002 and partial modification of the same, dated 23/5/2003, No.: 14477/MC/GS/Ethics/2003 dated: 21/4/2004 No: 12238/MC/GS/Ethics/2004 and No. MC/GS/05/32825 dated: 06/10/2005 & No.: MC/GS/05/37268 dated: 18/11/2005, office order dated: 06/05/2006, number: 16605/MC/GS/2006, office order dated: 21/06/2006 Number: 23811/MC/GS/2006 and office order dated: 07/09/2007, number: 26563/F.2(68)/MC/GS/07 & office order number: F.3(68)/MC/2008/10206 dated: 24/04/2008 order no. F.3(68)/MC/GS/2008/31279, dated: 01/11/2008 & F.MC/GS/2008/33069, dated: 15/11/2008, F.5(68)/MC/GS/2014/8832, dated: 19/03/2014 MC/GS/2014/34021 dated: 10/11/2014 from the office of the Principal, SMS Medical College& Controller of Attached Hospitals, Jaipur and letter from the Government of Rajasthan, Department of Medical Education, Group-1, Dated: 19th June, 2007, number: P015(6)/ME/GP-1/07 and order from the office of the Principal & Controller, dated: 21/08/2009, number: F.3(68)/MC/GS/2006/26114, **F.3(68)/MC/GS/2010/2524 dated: 28/01/2010, F.3 (68)/MC/GS/2011/9488 dated 23/04/2011 and F.3 (68)/MC/GS/2011/28449 dated 8/11/2011, F.3(68)/MC/GS/2011/23582 dated 30/08/2012, F.3(68)/MC/GS/2011/24118 dated 5/9/2012, F.5(68)/MC/GS/2014/243 dated 3/1/2014 and F.5(68)/MC/GS/2014/8832 dated 19/3/2014** the Ethics Committee has been re-constituted as follows:-

1. **Dr. V. N. Sharma**, Chairman – EC and Ex – Professor and Head Pharmacology, SMSMC, Jaipur and Ex – Principal, Medical Colleges, Jodhpur/Bikaner. **(Basic Medical Scientist)**
2. **Dr. R. K. Sureka,** Co – Chairman – EC, Ex – Professor, Department of Neurology and Ex – Additional Principal, SMSMC, Jaipur. **(Clinician)**
3. **Dr. Amitabh Dube**, Member Secretary – EC, Professor and Head, Department of Physiology, SMSMC, Jaipur.**(Basic Scientist)**
4. **Dr. Shashi Singhvi,** Member – EC, Ex – VC, RUHS and Former PHOD Department of Pathology, SMSMC, Jaipur **(Basic Scientist)**
5. **Dr. R. C. Gupta,** Member – EC, Ex – P HOD, Department of Physiology, SMSMC, Jaipur **(Basic Scientist)**
6. **Dr. (Mrs.) Ajay Yadav,** Member – EC, PHOD, Department of Pathology, SMSMC, Jaipur **(Basic Scientist)**
7. **Dr. S. D. Sharma,** Member – EC, Professor of Pediatrics, Medical Superintendent, JK Lon Hospital, SMSMC, Jaipur **(Philosopher)**.
8. **Dr. Arun Chougule,** Member – EC, Professor, Department of Radiotherapy, SMSMC, Jaipur **(Ethicist)**.
9. **Dr. Sudhir Mehta,** Member – EC, Professor, Department of Medicine, SMSMC, Jaipur **(Clinician)**
10. **Dr. Ashok Gupta,** Member – EC, Professor, Department of Pediatrics, SMSMC, Jaipur **(NGO Volunteer)**
11. **Dr. S. Sitaraman,** Member – EC, Professor, Department of Pediatrics, SMSMC, Jaipur **(Philosopher)**.
12. **Dr. Praveen Mathur,** Member – EC, Professor, Department of Pediatrics Surgery, SMSMC, Jaipur **(Clinician)**

13. **Dr. Monika Jain** Member – EC, Professor, Department of Pharmacology, SMSMC, Jaipur **(Basic Scientist)**
14. **Mr. I. S. Kavadia,** Member – EC, IAS (Retd.). **(Lay Person)**
15. **Dr. Gitika Kapoor,** Member – EC, Dean, R. A. Poddar Institute of Management, Jaipur **(Lay Person)**
16. **Dr. Devendra Kothari,** Member – EC, Director, Management Institute of Population & Development, Jaipur **(Lay Person)**
17. **Mr. Suresh Kumar Sahani,** Member – EC, Advocate, Rajasthan High Court. **(Legal Expert)**
18. **Mr. Vimal Choudhary,** Member – EC, Advocate Rajasthan High Court. **(Legal Expert)**

❖ **The Chief Account Officer/Representative** will be an invited member.

The Ethics Committee (EC) shall evaluate the scientific and Ethical aspects of all trials/projects/research works proposed to be conducted at the SMS Medical College & Hospital and its attached hospitals and grant approval/disapproval for the same.

The Ethics Committee of the SMS Medical College, Jaipur will be in compliance with the published guidelines of the Indian Council of Medical Research (ICMR) related to the conduct of clinical trials on human subjects. The working of the EC of the SMS Medical College, Jaipur will be as per the recommendation of the Drugs and Cosmetics (II[nd] Amendment) Rules, 2005 of the Ministry of Health & Family Welfare or any other rules/regulations pertaining to conduct of clinical trials.

This committee will examine and approve with or without modifications or disapprove submitted projects as per their scientific and ethical aspects. It will be the responsibility of the investigators to adhere to all applicable institutional/governmental rules and regulations while conducting their research/clinical trial.

The EC of the SMSMC is compliant with the published ICH-GCP Guidelines and also adheres to the ICMR guidelines and recommendations of the Drugs and Cosmetics (II[nd] Amendment) Rules, 2005 of the Ministry of Health & Family Welfare or any other rules/regulations pertaining to conduct of clinical trials.

The EC of the SMSMC reserves the right to cancel or to modify any approval/sanction/permission at any time if the conduct of the trial is not found to be compliant with the published guidelines of GCP-ICH or ICMR or Drugs and Cosmetics (II[nd] Amendment) Rules, 2005 of the Ministry of Health & Family Welfare and to the satisfaction of the Ethics Committee.

The EC approval/sanction/permission of the project concerned will be deemed cancelled/withdrawn if the Principal Investigator/Sponsor/Concerned party fails to submit the final trial closure report along with settlement of all pending payments within one month of the trial closure. The investigator will submit in writing at the time of trial closure a statement of total funding received from the sponsors and the details of receipts of Institutions dues/EC fees deposited by the PI for and in relation with trial. Besides this the PI shall also supply a list of project purchases and the relevant records as per prescribed Performa available in the EC office.

The Ethics Committee (EC) will continue to be in effect till further orders from the Office of the Principal and Controller, SMS Medical College & Attached Hospitals, Jaipur.

Submission of Clinical Trial Proposal to Ethics Committee for Consideration

Before being submitted to the EC for clearance, all projects will have to be presented and cleared by the SMS Medical College & Hospital Clinical Trials Screening Committee under the Office of the Principal and Controller, SMS Medical College, Jaipur. The plan proposals of M.D./M.S. and D.M./M.Ch. students would be routed through the Institutional Research Review Board and the Clinical Trials Screening Committee (CTSC), respectively. The reports of the IRRB and CTSC will be discussed in Institutional Ethics Committee. In case an issue needs further elaboration then the plan may again be taken up in the Institutional Ethics Committee meeting for the needful.

All Clinical Trial Agreements (CTA) will be tripartite with signatures of Head of the institution or his designee, principal investigator and the sponsor / representative of sponsor. The Head of the Institute will only be 'Proforma party 'and all other legal and financial responsibilities and liabilities will be of the principal investigator. The PI will furnish an undertaking on stamp paper of Rs. 10/- that he will abide by all the rules & byelaws and then only the agreement will be signed. Considering the sensitive and seriousness of the matter only qualified medical teachers/doctors should take up the Clinical Drug Trial research proposals and such work should not be entrusted to undergraduate/postgraduate students as Principal Investigator.

As per order from the **State Govt. order nos F.15(6)ME/Gr.1/03 dated 19/06/2007, P-15(6) ME/Gr-11/03 date: 19/09/2008, P.15 (6) ME/Gr.-1/03 dated 13-7-2010 and P.6(13) ME/Group-1/2009 dated 29/03/2011 and Office of the Principal & Controller , SMS Medical College, Jaipur office order nos 34053/F()/MC/GS/08 dated 25/11/2008, 26114 dated 21/08/2009, 5611 dated 03/03/2010, F-3(68)MC/GS/2009/17138 dated 17/06/2010, 19597/F3(68)/MC/GS/08 dated 13/07/2010, 18183/F3(68)/MC/General/08 dated 14/7/11 and MC/GS/2014/34021 dated 10/11/2014 regarding deposition of fees of Clinical Trials. The fees of Ethics Committee for per Clinical Trial will be 10% of project cost subject to minimum of Rs. 15,000 per project & this will be in the name of "RMRS, SMS Hospital (College Share), Jaipur" which is the account of the institution, SMS Medical College for this purpose. The rest of the funding for the trial shall be in the name of Principal Investigator.**

Both the cheques shall be submitted in the office of Account Office of Ethics Committee and account office of Ethics Committee shall distribute the cheque to Principal Investigator after obtaining receipt.

As per norms 10% of the total project is to be deposited at the time of signing the approved CTA inclusive of the sum of Rs 15,000/- that has to be submitted at the time of submission of the project. In case the project cost increases after signing of the contract the balance 10% cost has to be deposited for the needful.

PI will raise invoice for trial – related expenses as per period specified in CTA and send the same to Sponsor/CRO with a copy to the office of the P&C.
For investigator initiated trials without private funding, non – drug trial, trials by UG/PG/Ph.D. towards thesis/original research, and processing charges for Research sanctioned by state DST, Central DTS, ICMR, CSIR, etc., no Ethics Committee fees shall be charged as per P&C order No: 34053/F( )/MC/GS/08

dated 25/11/2008, and State Govt. order no: P-15(6) ME/Gr-1/03 dated: 19/06/2008, P.15 (6) ME/Gr.-1/03 dated 13-7-2010, and order no. P.6(13) ME/Group-1/2009 dated 29/03/2011. Any other project/research study of regional or national importance approved and with directions for the EC fees waiver by The Principal and Controller, S.M.S. Medical College and Attached Hospitals, Jaipur would also be entertained. The above mentioned trials should be submitted on the format approved by The EC for the purpose.

As per government guidelines, all clinical trials will need to be registered on the Clinical Trials Registry – India (CTRI), National Institute of Medical Statistics, ICMR website. The CTRI registration number and certification will have to be provided by the investigator / sponsor at the time of project submission of the EC.

The project / proposal will be submitted in eighteen (18) copies and can be submitted at any time. However, for the same to be considered in the next meeting of the EC, it needs to be submitted, complete in all respects, latest by second week of the preceding month in when the meeting is scheduled to be held. The date of the next meeting can be inquired from the office of the Ethics Committee.
The Principal Investigator (PI) or Co – Investigator designated by the PI will be required to make a power point presentation (maximum 5 slides and five minutes) before the EC and provide answers to the questions related to the project.
All attempts shall be made to send one set of all documents pertaining to a new project / trial submitted to the office of the Ethics Committee to each member of the EC at least one week before the meeting. In case any member is unable to attend the meeting and does not send his/her comments / questions / objections related to the project in writing to the secretary of the EC, his/her consent / approval for the trial will be presumed.

The EC will meet approximately every 6 to 8 weeks, earlier if needed, at a day decided by the Chairman, Secretary and the members at the last meeting.

The quorum of EC shall be at least 5 members with the following representations:

a) Basic Medical Scientists (preferably one pharmacologist)
b) Clinicians
c) Legal Expert (Advocate)
d) Social worker or NGO volunteer or Philosopher or Ethicist or Theologian
e) Lay Person

The Chairman of the EC will have the right to cancel the meeting and re-convene the same after a period of 30 minutes in case the quorum is not complete, A quorum of 5 members including a legal expert is essential to take decision.
A sub-committee for approval of minor changes in ongoing trials that have already been approved by the EC – like a protocol amendment, ICF update, IB update etc – can be constituted by the Chairman for expedited review of such matters which do not require the attention/meeting of the full EC.

The EC may invite as special invitee an expert on the subject related to the trial to be present during the discussion. However, he / she will not be part of decision making progress.

If one of the Ethics Committee member is submitting a trial for approval, during the final discussion and voting on the project, he / she will not be part of the decision making process.

The Project / Proposal must accompany the following enclosures for consideration for clearance:

a. One page synopsis of the study protocol.
b. Power Point presentation of overview of project (maximum 5 slides) on CD.
c. CTRI registration number & certificate.
d. Signed and dated Protocol containing all details of how the trial is to be conducted with version numbers and dates.
e. Signed and dated Investigator's Brochure containing all details of the chemistry, animal studies, toxicology and available clinical data of the trial drug with adequate bibliography.
f. Patient Information and consent form – in Hindi and English, with version numbers and dates, as per provision or schedule Y and DCGI permission letter. The ICF should be approved by EC before its use in the trial.
g. Permission letter from the Drug Controller General of India to conduct the trial of the drug in India.
h. Principal Investigator's current CV.
i. Every trial should have Principal Investigator (PI) and a Co – Principal Investigator (Co – PI) who should be a faculty member of the institution.
j. The Co-investigator's written permission about participation in the trial and to take over as PI if needed due to absence/transfer/retirement of PI is also required.
k. Copy of the Clinical Trials Agreement (CTA) (on format approved by the P&C) between the investigator and the Clinical Research Organization / Sponsor of the research project / trial and institution (proforma party)
l. Undertaking by the Investigator as per set format published in the Drugs and Cosmetics (IInd Amendment) Rules, 2005 of the Ministry of Health & Family Welfare (copy of the same may be obtained from the Office of the Ethics Committee). The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. As per the guidelines of DCGI under no circumstances the number of trials (that a PI can undertake) should be more than three at a time and the PI has to give an undertaking to this effect at the time of submitting the project.
m. Certificate for the investigator stating the number of trial he / she is presently actively engaged in and that he / she has the time and the resources to undertake the present study.
n. Fees for Drug Trial Clearance by EC to be 10% of the total project is to be deposited at the time of signing the approved CTA inclusive of the sum of Rs 15,000/- that has to be submitted at the time of submission of the project. In case the project cost increases after signing of the contract the balance 10% cost has to be deposited for the needful. D/D to be drawn in favor of "RMRS, SMS Hospital (College Share), Jaipur" which is the account of the institution, SMS Medical College for this purpose and submitted along with project.
o. Processing charges for Research sanctioned by State DST, Central DTS, ICMR, CSIR, etc to be **nil** of project cost.
p. The ICF should be according to conditions laid down in DCGI permission letter.
q. Compensation scheme for patients as per the guidelines of the Government of India.
r. Proposed financial / drug benefits to the patients.
s. Insurance Policy / Indemnification for the Investigator / Institution.

t. At the time of closure of the project a copy of audited account is to be submitted to the EC.
u. Any other relevant document pertaining to the trial (like subject recruitment procedure-advertisements & any other written information to be provided to subjects).

No deviations from, or changes of the protocol should be initiated without prior written EC approval / favorable opinion if an appropriate amendment except when necessary to eliminate immediate hazards to the subjects or when the changes(s) involves only logistical or administrative aspects of the trial.
The investigator should promptly report to the EC:

- In Case of SAE the PI shall inform the sponsor and the Ethics Committee within 24 hours of the SAE
- Deviation from or changes of the protocol to eliminate immediate hazards to the trial subjects.
- Changes increasing the risk to the subjects and / or affecting significantly the conduct of the trial.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Approval or disapproval shall be by consensus as far as possible. Reasons for disapproval of a trial will be conveyed to the Principal Investigator and he/ she will be given an opportunity to rectify same and submit the project for re-consideration.

Permission to conduct the trial shall be granted as per a set Proforma with the signatures of the Chairman and / or the Secretary of the Ethics Committee. The EC will look into the scientific and the ethical issues of the project / trial submitted and then grant approval / disapproval accordingly. Once approval is granted, it will be the sole responsibility of the investigator to adhere to the institutional / governmental rules and regulations while conducting their research / trial. It will not be the responsibility / liability of the EC in case there is any violation / infringement of this local rules / regulation by the investigator / sponsor while conducting their research / trial.

Once permission to conduct the trial is granted by the EC, it is **mandatory** on the part of the investigator to inform the EC about the progress of the trial on a regular basis, preferably every 6 monthly but earlier in case, any significant changes in the protocol / patient information forms, any serious or unexpected adverse effects of the trial drug and to provide a final report after the conclusion of the study. Non-Compliance with this may incur the withdrawal of approval by the committee.

As per ICMR guidelines, the investigator is mandated to submit an annual progress report of the trial to the EC along with any changes in the Patient Informed Consent Form or Patient Information Sheet, if any. On completion of the trial, the investigator is required to submit a completion report with a summary of the number of patients recruited the salient findings of the trial and synopsis of the adverse events observed during the trial. Non-compliance with this clause is liable to render the investigator to be blacklisted and barred from conducting clinical trials in the future in addition to cancellation of approvals for ongoing trial / trials.

Trials on human subjects in present day times are essential for the progress of science. Though primarily the responsibility for the ethical conduct of clinical trial and patient safety is of the Principal Investigator, the EC will also endeavor to ensure that these trials are done according to nationally and internationally laid-down guidelines ensuring at all times that the patient is not harmed.

The investigator should make sure that the research work conducted by him is in agreement with the guidelines of MCI for Medical Research.

(Dr. V. N. Sharma)
Chairman, EC
SMSMC, Jaipur
Phone No: 0141-2620692

(Dr. R.K. Sureka)
Co-Chairman, EC
SMSMC, Jaipur
Phone No: 0141-2368531

(Dr. Amitabh Dube)
Member Secretary, EC
SMSMC, Jaipur
Phone No: 0141-2518534