



SoMex Research & Health Ethics Committee

Standard Operating Procedures

As per resolution passed from the SoMex Research & Health Pvt. Ltd. and order from the Director of SoMex Research & Health Pvt. Ltd. Jaipur an Independent Ethic committee named "SoMex Research & health Ethics committee" was formed and further modified and extended constituting the following :

1. **Dr. S.G. Kabara, Chairman**, Director Legal Affairs & Medical Audit SDM Hospital, Jaipur 302017
2. **Dr. Rajkumari Somani, Member Secretary**, Director, Consultant Gynaecologist, Somani Hospital & Research Center, Jaipur
3. **Dr. Arvind Gupta, Member (Clinician)**, Consultant Physician & Diabetologist, Director, Diabetes Research Center, Jaipur
4. **Dr. N.K. Gurbani, Member (Biomedical Scientist)**, Former Head, Public Health Training Institute Jaipur
5. **Dr. Mukesh Sharma, Member (Clinician)**, Associate Prof. Dept. Of Ophthalmology, SMS Medical College, Jaipur
6. **Dr. Lokendra Sharma, Member (Pharmacologist)**, Asst. Prof. Dept. of Pharmacology, SMS Medical College, Jaipur .
7. **Mr. Chandra Shekhar, Legal Expert**, Advocate, Rajasthan High court, Jaipur
8. **Mr. Sanjay Srivastav, Legal Expert**, Advocate, Rajasthan High court, Jaipur
9. **Dr. Asha Hingar, Social Member**, Former Professor, Dept. Of Psychology, Rajasthan University, Jaipur
10. **Dr. Anil Kumar Garg, Member (Clinician)**, MBBS, 105-A, Vijay Nagar, 1st Kartarpura, Jaipur.
11. **Dr. Jaswant Goyal, Member (Clinician)**, Demonstrator, Mahatma Gandhi Medical College & Hospital, Jaipur
12. **Mrs. Abha Maheshwari, Social Member**, Mission heart Operation (A Non Government organization) Jaipur.
13. **Mr. Satya Narayan Modani, Member (Lay Person)**, Syam Nagar, Sodala, Jaipur
14. **Mr. Radha Mohan, Member (Lay Person)**, 31- Deep Nagar, Sodala, Jaipur

Constitution & Functions

Ethics committee is constituted and functions as per the schedule Y, ICH GCP guidelines and Good clinical practice guidelines issued by the Central Drug Standards Control Organization and Ethical guidelines for Biomedical Research on Human subjects, issued by the Indian council of Medical Research.

Version 2.0 dated 15 Nov 2011_SOPs_ SoMex Research & Health Ethics Committee, Jaipur, India
Prepared By: Dr. Anil Kumar Garg , Member (Clinician), SoMex Research & Health Ethics Committee
Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee
Approved By : SoMex Research & Health Ethics Committee

277, IIInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Bypass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com



SoMex Research & Health Ethics Committee

The Ethics Committee shall be an independent Ethics Committee for any Medical College/ Ayurved College/Homeopathic Medical College & Paramedical Institutions/ Pharmaceutical Organizations/Any other organization/ Individual interesting bio-socio medical research. Epidemiological surveys or any Clinical Trial for the benefit of the Human being shall be evaluated for the scientific and ethical aspects of all trials/projects research works proposed to be conducted and grant approval/disapproval for the same.

- The SoMex Research & Health Ethics Committee, Jaipur will be an Independent Ethics Committee, compliant with the published guidelines of the Indian Council of Medical Research (ICMR) related to the conduct of Clinical Trials on human subjects.
- This Committee will examine and approve or disapprove submitted research projects as per their scientific and ethical aspects.
- It will be the responsibility to the investigator to adhere to the locally applicable institutional/ government rules and regulation while conducting their research/trial.
- This ethics committee will continue to be in effect till further orders from the Office of the Director, SoMex Research & Health Pvt. Ltd. Jaipur.

- : Submission of Clinical Trial Proposal to Ethics Committee for Review :-

- All projects to be submitted will be reviewed by the concerned department and forwarded through the Head of the Department of the Ethics Committee office.
- The Project/Proposal will be submitted in Sixteen (16) 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 the 02 weeks prior to proposed EC meeting date.

Meeting of Ethics Committee

- The EC will meet once every two month- on the first Friday/Saturday of every alternate month if research proposal are before the Ethics committee for review.
- If this is a government holiday or meeting not being convened on proposed meeting date the EC will meet on the subsequent Friday/Saturday.

Version 2.0 dated 15 Nov 2011 SOPs_ SoMex Research & Health Ethics Committee, Jaipur, India
Prepared By: Dr. Anil Kumar Garg , Member (Clinician), SoMex Research & Health Ethics Committee
Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee
Approved By : SoMex Research & Health Ethics Committee

277, IInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Bypass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com



SoMex Research & Health Ethics Committee

- The Chairman is empowered to call the expedite meeting of Ethics Committee at a notice of seven days besides the regular meeting.
- A quorum will be defined as one – half of the regular members of the committee; as per the Schedule Y (20th January 2005), the quorum must include members with the following representations:
 - A. At Basic Medical Scientist (Preferably one pharmacologist).
 - B. One Clinician
 - C. One legal expert
 - D. One social scientist, representative of non governmental agency/ Philosopher/ ethicist/ theologian or a similar person.
 - E. One lay person from the community.
- 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 sub-committee comprising of ethics committee members nominated by the Ethics Committee to approve minor changes in ongoing trials that have already been approved by the EC-like a protocol amendment, ICF update etc- can be constituted by the Chairman for expedited review of such matters which do not require the attention of the full EC.
- The EC will request in writing that the Principal Investigator or his/her representative be available for discussion/classification during the time the committee is considering the proposal for approval.
- The EC may invite as special invitee an expert on the subject related to the trial to be present during the discussion.
- Approval or disapproval shall be by consensus• Reasons for disapproval of a trial will be conveyed to the Principal Investigator in details and he/she will be given an opportunity to rectify the same and submit the project for re-consideration.
- If one of the Ethics Committee members is submitting a trial for approval, during the final discussion of approval or otherwise of the project, he/she will not be the part of decision making process.

Version 2.0 dated 15 Nov 2011 SOPs SoMex Research & Health Ethics Committee, Jaipur, India
Prepared By: Dr. Anil Kumar Garg, Member (Clinician), SoMex Research & Health Ethics Committee
Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee
Approved By : SoMex Research & Health Ethics Committee

277, IInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Byepass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com



SoMex Research & Health Ethics Committee

Documents to be Submitted

- The Project/Proposal must have the following enclosures to be accepted for consideration for clearance:-
 - A. Signed and dated protocol containing all details of how the trial is to be conducted with version numbers and dates.
 - B. Signed and dated Investigator and available clinical data of the trial drug with adequate bibliography.
 - C. Patient information and consent form- in Hindi and English, with version numbers and dates.
 - D. Permission letter from the Drug Controller General of India to conduct the trial of the drug in India. A conditional approval for a trial may be granted with the condition that the same may be submitted later in cases where the permission to conduct the trial has been applied for and approval is awaited from the DCGL.
 - E. Principal Investigator's current signed and dated CV.
 - F. Copy of the Clinical Trials agreement between the investigator and the Clinical research organization/ sponsor of the research project/ trial, if applicable.
 - G. Undertaking by the Investigator as per set format published in the Drug and Cosmetics (11th amendment) Rules 2005 of the Ministry of Health & Family Welfare (Copy of the same may be obtained from the Office of the EC)
 - H. Compensation scheme for patients.
 - I. Proposed financial/ drug benefit to the patient
 - J. Insurance policy/ Indemnification for the investigator/ Institution.
 - K. Any other relevant document pertaining to the trial (Like subject recruitment procedures- advertisement & any other written information to be provided to subjects)
 - L. The EC may request additional information than outlined in the ICF to be given to subject when, in the judgment of EC, the additional info would add meaningfully to the protection of the right, safety, and/ or well being of the subject.

Processing Fee

- (1) **Processing fee** for project sponsored by pharmaceutical company will be Rs. 20000/- and the extra processing fee of Rs. 10000/- will be charged if a special

Version 2.0 dated 15 Nov 2011_SOPs_ SoMex Research & Health Ethics Committee, Jaipur, India
Prepared By: Dr. Anil Kumar Garg, Member (Clinician), SoMex Research & Health Ethics Committee
Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee
Approved By: SoMex Research & Health Ethics Committee

277, 11th Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Bypass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com



SoMex Research & Health Ethics Committee

meeting is to be called for the processing of the project apart from the regular meeting.

- (II) **Processing fee** for project sponsored by Govt. agencies/Investigator initiated trials/Research scholars/ will be Rs. 10000/- and the extra processing fee of Rs. 10000/- will be charged if a special meeting is to be called for the processing of the project apart from the regular meeting.
- (III) **Processing fee** for any amendment in trial related documents will be 5000/-Rs. and the extra processing fee of Rs. 10000/- will be charged if a special meeting is to be called for the processing of the project apart from the regular meeting.
- (IV) **The fee is to be paid by cheque/DD in favor of "SoMex Research & Health Pvt. Ltd." payable at Jaipur. (PAN No. - AALCS4343Q).**

Duties of Principal Investigator / Site

No deviations from, or changes of, the protocol should be invited without prior written EC approval/favorable opinion of an appropriate amendment except when necessary to eliminate immediate hazards to the subject or when the changes(s) involves only logistical or administrative aspects of the trial.

The Investigator should promptly report to the EC:-

- A. Deviation from or changes of, the protocol to eliminate immediate hazards of the trial subjects.
- B. Changes increasing the risk to the subjects and/or affecting significantly the conduct of the trial.
- C. New information that may affect adversely the safety of the subject or the conduct of the trial.

•Permission to conduct the trial shall be granted as per a set Performa with the signatures of the Chairman and/or the Secretary of the Ethics Committee• It will be responsibility of the investigator to adhere to the institutional/ governmental rules and regulations while conducting their research/trial.

Version 2.0 dated 15 Nov 2011_SOPs_ SoMex Research & Health Ethics Committee, Jaipur, India

Prepared By: Dr. Anil Kumar Garg, Member (Clinician), SoMex Research & Health Ethics Committee

Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee

Approved By : SoMex Research & Health Ethics Committee

277, IIInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Bypass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com



SoMex Research & Health Ethics Committee

• 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, 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 patients recruited the salient findings of the trial and synopsis of the adverse events observed during the trial.
- Non-compliance with these clauses is liable to render to investigator to be blacklisted and barred from conducting clinical trials in the future.

Trials on human subjects in present-day-times are essential for the progress of sciences to serve the humanity better. It will be the responsibility of both, the investigator as well as this EC to ensure that these trials are done according to nationally and internationally laid-down guidelines ensuring at all times that these trials are being done in a most ethical ways and the patients are preferred over society and science.

Dr. Rajkumari Somani
Member Secretary,
SoMex Research & Health Ethics Committee

Dr.S.G.Kabara
Chairman
SoMex Research & Health Ethics Committee

Version 2.0 dated 15 Nov 2011_SOPs_SoMex Research & Health Ethics Committee, Jaipur, India

Prepared By: Dr. Anil Kumar Garg, Member (Clinician), SoMex Research & Health Ethics Committee

Reviewed By: Dr. Rajkumari, Member Secretary, SoMex Research & Health Ethics Committee

Approved By : SoMex Research & Health Ethics Committee

277, IIInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopal pura Bypass, Jaipur-302019

Phone: 0141-2504996, 3212996 Fax: 0141-2504110

E-mail: ec@somexresearch.com Web: www.somexresearch.com