Somani Hospital Ethics Committee

Somani Hospital Ethics Committee,

Jaipur, Rajasthan, India

Standard Operating Procedure (SOP)

Version 1.4 dated 01 JUNE 2022_EC SOP

EC Registration No.: ECR/1531/Inst/RJ/2021 issued date 06-Apr-2021

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PREPARED BY:

Name: Dr. Manohar Lal Bhatia — Designation: Basic Medical Scientist (Pharmacologist)

Signature: — Date: 01 June 2022

REVIEWED BY:

Name: Dr. Nupur Kasliwal — Designation: Member Secretary

Signature: — Date: 01 June 2022

APPROVED BY:

Name: Dr. Vishnu Bhutia — Designation: Chairperson

Signature: — Date: 01 June 2022

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR

Address

Somani Hospital, 27/1, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur-302019

Phone : 0141- 2504996, 8104124996

E-mail : ecsomanihospital@gmail.com • Web.: www.somanihealthcare.com

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Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

Address

Somani Hospital, 274, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019

Phone : 0141- 2504996, 8104124996

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I. ABBREVIATIONS

ADR- Adverse Drug Reaction

AE- Adverse Event

CFR- Code for Federal Regulation

CIOMS- Council for International Organizations of Medical Sciences

CRF- Case Repot Form

CTA-Clinical Trial Agreement

DCGI- Drug Controller General of India

DSMB-Data Safety Monitoring Board

FDC- Fixed Dose Combination

GCP-Good Clinical Practice

GMP- Good Manufacturing Practice

IB- Investigator Brochure

ICF- Informed Consent Form

ICH-International Conference on Harmonization

ICMR-Indian Council of Medical Research

IND- Investigational New Product

IP-Investigational Product

IRB- Institutional Review Board

LAR- Legally Acceptable Representative

NDA- New Drug Application

PI-Principal Investigator

RCT- Randomized Controlled Trial

SAE-Serious Adverse Event

SIV- Site Initiation Visit

SOP- Standard Operating Procedure

SHEC- Somani Hospital Ethics Committee

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SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN

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II. REFERENCES

- New Drugs and Clinical Trials Rules 2019
- ICH Harmonized Tripartite guideline GCP, dated 10 June 1996
- E6(R2) GCP guidelines: addendum to ICH E6(R1) dated March 2018
- GOOD Clinical Practices (GCP) Guidelines issued by the Central Drugs Standard Control Organization. Directorate general of health services, Government of India
- Ethical guidelines for biomedical research on human participants by ICMR, New Delhi.
- Drug and Cosmetic Act (3rd amendment 8 Feb 2013)
- Drug and Cosmetic (IInd amendment) Rules, 2016
- Gazette Notification G.S.R. 889(E) dated 12th Dec, 2014
- Gazette Notification G.S.R. 611(E) dated 31st July, 2015
- Gazette Notification G.S.R. 69(E) dated 03st Feb, 2015
- Gazette Notification G.S.R. 11(E) dated 6th Jan, 2016
- Gazette Notification G.S.R. 287(E) dated 08st Mar, 2016

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STANDARD OPERATING PROCEDURE (SOP)

1. INTRODUCTION AND AUTHORITY UNDER WHICH SHEC WAS ESTABLISHED:

SHEC is an Institutional Review Board established under the authority of Somani Hospital to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by among other things, reviewing and approving/providing favorable opinion on the proposed trial protocol, the suitability of the investigator, facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

2. SCOPE OF SOMANI HOSPITAL ETHICS COMMITTEE (SHEC):

The scope of SHEC shall be to review any Phase II, Phase III or Phase IV and BA/BE clinical trial to be conducted by any investigator at Somani Hospital and other hospitals which are located within the same city or within a radius of 50kms of the Somani Hospital.

The SHEC may undertake the review and monitoring of clinical trial protocols of other investigator(s) and site(s) who do not have their IEC, after confirming that the other sites are within the loco-regional and community setting similar to the SHEC. SHEC should ensure that such trial site(s) have proper arrangements to conduct the trial and SHEC will take all the responsibility for the study review and regular monitoring as per rules and regulations.

The SOP and management of SHEC will be in the line of guideline given in New Drugs and Clinical Trials Rules 2019 and, ICH- GCP, and WHO guidelines.

- Voluntarism
- Informed Consent
- Privacy
- Confidentiality
- Risk Minimization
- Professional Competence

To maintain the ethical conduct of the departments, at the highest professional level, to educate the staff concerning ethical norms, to endeavor to protect the patient against willful misconduct of the hospital and to aid Somani Hospital in achieving its objectives.

3. RESPONSIBILITIES:

SHEC is an appropriately constituted Institutional Review Board/Institutional Ethics Committee which will work independently without any personal interest for Institution in any aspect. The basic responsibilities of the committee shall be to safeguard the welfare and the rights of the subjects

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participating in a clinical trial. Special attention should be paid to trials that may include vulnerable subject and involving special therapeutics.

The Ethics Committee is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programs till the same are completed and review any long term adverse or beneficial effects repeated even beyond the study.

Such an ongoing review is in accordance with the Declaration of Helsinki and all the International guidelines for biomedical research, further it may be revised and reviewed from time to time.

The responsibility of SHEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free any bias and influence that could affect their objectivity. The committee shall provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

Responsibilities of the SHEC can be defined as follows:-

- To protect the dignity, rights and well-being of the potential research participants.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in the development and the education of a research community responsive to local health care requirements.

3.1 ROLE &RESPONSIBILITIES OF ETHICS COMMITTEE MEMBERS INDIVIDUALLY:

S. No.	Member of EC	Definition/description/Responsibility
1	**Chairperson**	➢ Conduct EC meetings and be accountable for independent and efficient functioning of the committee ➢ Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations ➢ Rectify minutes of the previous meetings ➢ In the absence of Chairperson at a planned meeting, the Chairperson should nominate an Acting Chairperson into present EC members or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. ➢ Seek COI declaration from members and ensure quorum and fair decision making. ➢ Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

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2	Member Secretary	➢ Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review ➢ Schedule EC meetings, prepare the agenda and minutes ➢ Organize EC documentation, communication and archiving ➢ Ensure training of EC secretariat and EC members ➢ Ensure SOPs are updated as and when required ➢ Ensure adherence of EC functioning to the SOPs ➢ Prepare for and respond to audits and inspections ➢ Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. ➢ Assess the need for expedited review/ exemption from review or full review. ➢ Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. ➢ Ensure quorum during the meeting and record discussions and decisions.
3	Basic Medical Scientist(s)	➢ 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.
4	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 car, management and compensation. ➢ Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	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 ➢ Evaluation of Contract and Budget to ensure protection of research participants, indemnification and compensation
6	Social scientist/	➢ Ethical review of the proposal, ICD along with the translations.

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Address

Somani Hospital, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019

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	philosopher/ ethicist/ theologian	➢ 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.
7	Lay person(s)	➢ Primary reviewer for the informed consent document language- whether it would be understandable to the subjects. ➢ 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 social concerns. ➢ Assess on societal aspects if any.

4. OBJECTIVES:

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICH-GCP, New Drugs and Clinical Trials Rules 2019 and ICMR guidelines for biomedical research on human subjects, local laws and regulatory authority of India.

In addition to these guidelines, the ethics committee shall follow the Drug and Cosmetics (III Amendment) Rules, 2013 of the Ministry of Health & Family Welfare or any other rules/regulations, applicable and in force time to time, pertaining to conduct of clinical trials.

The EC will work for the studies to be conducted at Somani Hospital and other Hospitals which are situated under 50 kilometers radius of Somani Hospital.

The EC will be independent in its functioning and decision making for all the proposal of clinical trial and their related activities.

5. COMPOSITION OF SHEC:

Our EC comprise of members from varying background to promote to complete and fair review of human clinical trial projects conducted at our site. There is representation from both genders in committee. The ethics committee will comprise a minimum seven members and up to fifteen members. The Chairperson of the committee shall be a senior head (retired/ working) from any reputed Institution/ Department. The other members should have various backgrounds to promote complete and adequate review of research activities. It includes:

I. Basic Medical Scientist (preferably one pharmacologist)
II. Clinicians
III. Legal Expert

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SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • MEMBER SECRETARY

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • CHAIRMAN

Address
Somani Hospital, 1277, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019
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IV. Social scientist or representative of non-governmental voluntary agency or philosopher or Theologian or Ethicist

V. Lay person from Community

- **Refer Annexure "B" for Member list of EC**

A quorum (As per New Drugs and Clinical Trials Rules 2019) must be present at each meeting. "Confidentiality and conflict of Interest agreement from for SHEC members (as Annexure C)" must have been signed by all the SHEC members. The entire member's agreement will be signed by chairperson of SHEC and in case of Chairperson the same will be signed by Member Secretary of the SHEC.

A minimum of 5 members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals. The Quorum requirement is as follows-

A) Basic Medical Scientist
B) Legal Experts
C) Social scientist/ Representation of non- governmental voluntary agency
D) Clinician
E) Lay Person

The SOMANI HOSPITAL Ethics Committee will ensure as the cardinal principles of research ethics viz autonomy beneficence non malfeasance and justice are taken care of in planning conduct and reporting of a proposed study it will look into the aspects of informed consent process risk benefit ratio distribution of burden/ benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study though periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements applicable guidelines and laws.

- The licensing authority will be informed by SHEC in writing in case of any changes takes place in the membership of EC.

5.1 APPOINTMENT OF NEW MEMBER:

The selection and appointment of new member would be done by SHEC Chairperson with the approval of Somani Hospital Management. The selection of Chairperson would be suggested by SHEC members and the recommendations may be sought from the SHEC chairperson, same would be selected by Somani Hospital management.

A new member will give "Joining consent" as per Annexure-D

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5.2 DURATION OF MEMBERSHIP:

The members of SHEC will be appointed for duration of 5 years, unless it is sooner updated as per requirement. The members can be continued and there will be no limit on the number of times the membership is extended. Extension of membership will be based on the recommendation of the Somani Hospital Ethics Committee or till willingness of the member.

- **Refer Annexure "E" for Extension Consent for old members.**

5.3 RESIGNATION/REPLACEMENT PROCEDURE:

The members who have resigned may be replaced at the discretion of the new member selection procedure. SHEC members who decide to resign must provide their proposed resignation letter 20 days prior to the next scheduled meeting.

5.4 REMOVAL OR TERMINATION PROCEDURE :

A member may be relieved or terminated of his/her membership in case of:-

- The member can be removed in case if he/she is found not meeting up the standards of an eminent member. The member will be removed by the chairman along with consensus of the 5 members.
- If any member fails to attend more than 4 meetings of SHEC. The membership shall be reviewed by the SHEC, if the member is a regular defaulter. If deemed necessary, the SHEC may decide to terminate the membership.
- Members seeking payments or financial obligation from SHEC, Providing wrong information about them or involved in any proved/documented antisocial/criminal activity will be disqualified with immediate effect by the Chairman

In all such situations/circumstances, chairperson of SHEC 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 SHEC meeting and SHEC membership list will be revised.

5.5 TRAINING AND CONFIDENTIALITY:

- All members of SHEC will be trained on ICH-GCP, New Drugs and Clinical Trials Rules 2019 and other regulatory requirements time to time so that they become aware of their roles, responsibilities and regulations.
- All relevant information on ethics will be brought to the attention of members of SHEC by the Member Secretary.
- SHEC Members will be encouraged to attend national and international training programs/conferences/ seminars in the field of research to help in improving the quality of research protocols ethics committee submissions and review.

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- All the members will be trained once in a year or when needed time to time for the updating the new rules and Applicable guidelines for Biomedical Research in India.
- All the members should be trained for New Drugs and Clinical Trials Rules 2019 and GCP guideline and other regulatory requirements for clinical trials in India to safeguard the rights, safety and well-being of the trial subjects.

Refer "Annexure-F" (format of training log)

6. CONFIDENTIALITY AND CONFLICT OF INTEREST:

Each member of SHEC will sign the confidentiality and conflict of interest agreement on joining and will ensure to work as independent body without biasing for institute or personal.

Any member will not disclose any information related to study outside from institute/IEC.

Refer Annexure "C" for confidentiality and conflict of interest.

7. OPERATING PROCEDURE:

7.1 MEETING SCHEDULE:

The committee will meet at least **once in every three months** on the second Saturday/ Sunday. Advance notice will be sent to all EC members at least 10 days before each meeting along with agenda.

The Chairperson will conduct all meeting of the SHEC. If for reasons beyond control the chairperson is not available an alternate Chairperson will be elected by the members present from among themselves for that meeting.

The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/ She will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

COVID related studies will be discussed on fast track mode, EC meeting could be arranged within 7-10 days after receiving the EC dossier and EC decision will be released within a week to PI.

7.2 APPLICATION PROCEDURE :

- The Principal Investigator can submit research proposal to the SHEC for review and approval.
- The Project/ Proposal will be submitted in Eleven (11) copies.
- The PI will submit appropriate copy/ copies (hard and soft copies) of the study related documents to the member secretary.

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- The proposal can be done in the form of soft copies in CD/DVD should be accompanied with at-least one hard copy of total submission.
- Soft copy i.e. CD/ DVD having all submitted documents in PDF format with indexing as described in submission letter.
- Member Secretary will stamp, sign and date of receipt on the cover letter confirming receipt of the documents and a photocopy of the same give to the applicants for their records. Missing information should be supplied within two weeks (if there is any).
- The researchers should be submitted their proposal in an appropriate application to IEC in the prescribed format of the New Drugs And Clinical Trials Rules 2019, along with the study protocol at least **two weeks** in advance to a schedule EC meeting.
- No subject shall be recruited to the proposed trial before the written approval/ favorable opinion issued by EC.
- A fee as per annexure -A (with all required documents) should be submitted before the meeting is held.
- The ethics committee will not under usual circumstances take up more than 3 new proposals for clearance in one sitting. To avoid inconvenience to researchers' additional meeting can be called by chairperson within a week.
- The decision will be communicated in writing within 7 working days after the meeting. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
- The chairperson may approve a proposal without holding a formal meeting only condition like
  - The proposal or amendment to protocol/ ICF involves only administrative changes and no risk to the subject
  - Proposed protocol reviewed in a previous meeting and given some suggestion and the sponsor amended as suggested
- In such conditions, the chairman has to inform immediately to all the members of SHEC regarding such an expedited approval and document the decision, except when the suggestion/ change was not recorded in the minutes of meeting.

7.3 REVIEW PROCEDURE:

- Meetings of SHEC shall be held on intervals as prescribed (once in two month).
- **For studies on COVID treatment or Vaccine or such type of studies will be reviewed on priority basis and (expedited) meeting can be arranged any time to discuss the study.**
- PI should ensure that EC review fee should be received prior to conduct of EC meeting.
- The proposals will be sent to members at least 10 days in advances.
- At the time of presentation, the PI shall make a presentation for not more than 15-20 minutes

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- Decision will be taken by consensus after discussion and voting will be done if necessary.
- Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
- The decision of the meeting shall be recorded and shall be confirmed during the next meeting with signature of chairperson.
- Minutes of meeting will be maintained in which decision of EC during the meeting, approval and signature of all presented member will be documented.
- The ICF will be approved by the ethics committee. Approved ICF should be used by the site for consenting.
- If any of the EC member is submitting a trial for approval during the final discussion of approval or otherwise of the project he /she will not the part of the decision making process.
- Checklist for review of scientific validity and assessment of risk vs benefit
  (Refer annexure 'M')

7.4 INDEPENDENT CONSULTANTS:

SHEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects specific disease or methodologies or represent specific communities' patient groups or special interest groups e.g. cancer patient HIV/AIDS positive or ethnic minorities. They will not take part in the decision making process.

Independent Consultant should give Confidentiality Agreement form to SHEC before attending the meeting.

Refer Annexure- "G" (Confidentiality Document form)

8. ELEMENTS OF REVIEW:(Before Approval)

- Scientific design and conduct of the study.
- PI qualification and experience in clinical trial.
- Protocol specific requirements such as experienced and adequate site staff, infrastructure, site facilities with PI.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks harms and potential benefits.
- Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and issues like sample size and advertisement details.
- Recruitment strategies to be used
- Management of research related injuries adverse events and compensation provisions.
- Insurance if available then expiry/validity of it.

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- Justification for placebo in control arm, if any.
- Availability of products to the trial subjects after the study, if applicable.
- Patient information sheet and informed consent form in English/ Hindi and local language.
- The SHEC will ensure that adequate provisions are made for obtaining the assent of the children based on the age, maturity, and psychological state of the children.
- Protection of privacy and confidentiality of subjects.
- Rights and responsibilities of subject shall be documented and are specified. Subject's participation and withdrawal from the trial shall be voluntary (as also documented in ICF).
- Compensation to subjects as per the guideline of the Government of India.
- Involvement of the community, wherever necessary.
- Protocol and Performa of the study including the consent form.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators research and supporting staff.
- The information regarding payment to subjects including the methods amounts and schedule of trial subject, (preferably prorated) is set forth in the written informed from and any other written information to be provided to subjects.
- Provision for the Academic Study would be made as per the Gazette Notification G.S.R. 11(E) dated 16th March,2016
- The ICF and Audio-Visual recording of the consent should be according to conditions laid down in DCGI permission letter and the gazette notification 611 (E) dated Jul 31,2015
- Waiver letter for AV consenting for any COVID related study.

8.1 REVIEW OF CONTRACT AND BUDGET:

This is primary responsibility of Legal Expert to review & analysis of the Clinical Trial Agreement and proposed budget with regards to patient safety and well-being. Legal person should review following in the agreement:

- Insurance for trial participants and its amount should be justified and its validity
- Compensation for patient for travel
- Compensation for any SAE if occurred during the study period
- Overall review for indemnification and compensation for trial subjects

9. APPROVAL/ DISAPPROVAL:

In case of no consensus among all the members a voting process will be initiated by the member secretary. If the majority vote completes the quorum then the study would be considered as approved.

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Approval/ Disapproval shall be by consensus.

Permission to conduct the trial shall be granted in writing to the investigator with the signature of the Chairperson/Member Secretary.

Reason 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.

- The recruitment of subject shall be started only after written approval from EC and Regulatory authority received.
- Conflict of interest should be declared prior to the review and documented.
- Approval will be given after the analysis of risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.
- CTRI Registration required before recruitment of subject.
- DCGI approval for site and PI should be provided prior to recruitment of subject.

10. EXPEDITED REVIEW:

In case of some specific clinical research projects the EC may consider the need for an expedited review. Such projects need to have a valid rationale for expedite review. The members of the EC will ensure that such projects are involved with no more than a minimal risk to the study participants. Such reviews will be undertaken by the chairperson or any one of the experienced members designated by the chairperson.

COVID related studies or any other studies related to pandemic disease will be reviewed on fast track mode and expedited meeting will be arranged within 7-10 days after receiving the EC dossier.

11. ONGOING REVIEW:

The committee will conduct ongoing review of clinical research projects at regular intervals, but not less than once in a year. The EC can visit the clinical trial site/Department to conduct and on-site review. Such visits can include the review of the following documents at the site:

- Signed informed consent forms (with their updated amendments) and other related source documents
- Observation of administration of the informed consent process
- All serious and unexpected and/or related adverse events reports
- Completed case report forms
- Amendments of the protocol or other essential documents
- Advertisements, if any for the subject recruitment
- Protocol Deviations and non-compliance evaluation

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

Address

Somani Hospital, 27, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019

Phone : 0141- 2504996, 8104124996

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The EC can conduct an Audit visit at the site in case of any non-compliance reported to the EC. These reports may follow information to the EC from the study subjects, public, sponsors, progress reports and safety reports. The EC will review such allegations of non-compliance and assess whether such allegations/alleged practices would cause injury or other unanticipated harm or risk to subjects or others involved in the trial. In such cases of alleged non-compliance, the EC may suspend the trial following a review by the full committee. Such decisions will be intimated to the Investigator and the Sponsor in writing.

- Review of amendments to the originally approved protocol and its related documents i.e. ICF and IB should be done for the assessment of risk to the trial subjects.

11.1 DETECTION OF PROTOCOL DEVIATION/ NON-COMPLIANCE/ VIOLATION

The Protocol deviation/non-compliance/violation can be detected in any of the following ways:

1. The Institutional Ethics Committee members performing monitoring of the project at trial site can detect protocol deviation/non-compliance/violation.

2. The Member Secretary or IEC coordinator can detect protocol deviation/non-compliance/violation for failure to comply with statutory requirements/failure to respond to requests from Institutional Ethics Committee within reasonable time limit/failure to respond to communication made by Institutional Ethics Committee.

3. The Principal Investigator himself may forward protocol deviation/non-compliance/violation reports to inform the Institutional Ethics Committee.

4. The monitor (CRA) identifies the deviation and inform to PI or other study team.

11.2 NOTING PROTOCOL DEVIATION / NON-COMPLIANCE / VIOLATION BY THE MEMBER SECRETARY:

• The IEC members who have performed monitoring of a particular trial site and detect protocol deviation/non-compliance/violation will inform the Member Secretary or IEC coordinator.

• Member Secretary or IEC coordinator would keep record of protocol deviation/non-compliance/violation from the project files/protocol deviation/non-compliance/violation letters forwarded by the Principal Investigator or forwarded by IEC members.

• Whenever protocol deviation / non-compliance / violation has been observed the Member Secretary will ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the Full Committee Institutional Ethics Committee meeting.

•The ethics committee should evaluate protocol violations to make sure to track for injury to the subject due to noncompliance of protocol. Institutional Scientific

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

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11.3 NOTIFICATION TO THE PRINCIPAL INVESTIGATOR:-

• The Member Secretary or IEC coordinator will send a recommendation letter signed by the Institutional Ethics Committee Chairperson or member secretary to the Principal Investigator if the decision was 'request the Principal Investigator not to perform such deviations/non-compliances/violations in future'.

• The Member Secretary or IEC coordinator will send a project suspension/termination letter signed by the Institutional Ethics Committee IEC Chairperson or member secretary to the Principal Investigator if the decision was 'suspend the study till information available/terminate approval of the current study'.

• If the decision was 'refusal of subsequent project applications from the Principal Investigator, this notification letter signed by Institutional Ethics Committee Chairperson or Member Secretary will be sent to the Principal Investigator.

• The copy of Project suspension/ project termination/ Principal Investigator notification of refusal to accept application from him/her due to Non-compliance will also be sent to the DCGI/Sponsor.

• One copy of all the letters is kept in the project file by the Member Secretary or IEC coordinator.

• The Member Secretary or IEC coordinator will maintain a file that identifies investigators who are found to be non-compliant at monitoring visits or with national/international regulations or who fail to follow protocol

(Refer Annexure 'N' for deviation report form)

12. INTERIM REPORTS:

The Investigator must submit a progress report on the clinical trial yearly to EC from the date of first approval with respect to specific study.

Following details should be mentioned in the report:

- Number of subjects screened, enrolled, completed and withdrawn/lost to follow up
- Current status of study
- Any safety issues i.e. SAEs

13. FOLLOW-UP PROCEDURES:

1) Final report should be submitted at the end of study including a copy of the report which has been to sponsoring agency.
2) All SAE and the interventions undertaken should be intimated immediately to SHEC. The PI should submit the SAE's reported by other centers from time to time to the Member Secretary for information to SHEC along with comments if any action is required in the current study.
3) Protocol deviation if any should be informed.

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4) Any amendment to the protocol should be submitted for approval.
5) Any new information related to the study should be communicated to SHEC.
6) Premature termination of study should be notified with reasons along with.
7) Change of investigators should be done with the approval of SHEC.

14. RECORDS KEEPING AND ARCHIVING:

All documentation and communication with SHEC are to be dated, filed and preserved according to written procedures and as per applicable rules and regulation as mentioned in the New Drugs and Clinical Trial Rules,2019. Strict confidentiality is to be maintained during access and retrieval procedures. The following records should be maintained for the archiving:-

1) The Constitution and composition of the IEC.
2) Signed and dated curriculum vitae of all the members of IEC.
3) Standard operating procedures of the IEC.
4) National and International guidelines.
5) Copies of protocols submitted for review.
6) All correspondence with IEC members and investigators regarding application decision and follow up.
7) Agenda of all IEC meetings
8) Minutes of all SHEC meetings with signature of the Chairperson.
9) Copies of decisions communicated to the applicants.
10) Record of all notification issued for premature termination of a study with a summary of the reasons.
11) All safety reports submitted to EC and Final report of the study including microfilms, CDs and video recordings.

All records must be safely maintained after the completion/termination of the study for a minimum period **of 5 years from the date of completion or termination of the trial** (Both in hard and soft copies).

14.1 RECORD RETRIEVAL

In case of any Inspection or audit of SHEC by any Regulatory agency a prior notification should be given to EC and all the trial related documents will be provided to Regulatory agency for the audit or inspection. The documents related to the clinical trial projects reviewed by the EC can be inspected by the regulatory agencies.

15. CORRESPONDENCE:

The ethics committee will only operate from following address;

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee
Somani Hospital, 277, Shri Gopal Nagar, 80 Feet Road, Gopalpura Byee pass,
Jaipur-302019, Rajasthan, India.
Phone No-0141- 2500996 Fax No-0141- 2504110
Email id- ecsomanihospital@gmail.com

All correspondence to be done either in the form of written communication, e-mail or phone preferred mode of communication for all than patients is e-mail.
Meeting with EC Chairperson is only thought prior appointment for all other than patient.

16. VULNERABLE GROUPS:

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

A. Research on genetics should not lead to racial inequalities.

B. Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

C. 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 form the legal guarding (LAR-Legally acceptable Representative) should be taken after the person is well informed about the study, need for participation risks and benefits involved and the privacy and confidentiality procedure. The entire consent process should be properly documented.

D. Adequate justification is required for the involvement of participants such as prisoners, students, pregnant women, children, handicapped or mentally disabled persons, displaced persons, subordinates, and employee's service personnel etc. who have reduced autonomy as research participants since the consent provided may be under duress or various other compelling reasons.

17. SAFETY REVEIW PROCEDURES:

- All the SAE follow up has to be done in accordance to the said guidelines and has to be compensated as per regulatory guidelines **"CHAPTER VI rule number 42 of New Drugs and Clinical Trials Rules 2019"** and should be reported to regulatory authority as per rules and regulation.
- All serious adverse events that occur at the site are reported to the EC and Sponsor within 24 hours from the date they come into notice by the Investigator.

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • MEMBER SECRETARY

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • CHAIRMAN

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- In case of any adverse events, the investigator must send the same in the interim report to the EC within 14 days.
- SAE shall be addressed and appropriate medical care to be provided to the patient, reported as per applicable rules and regulations.
- All safety reports will be addressed to the chairperson/ member secretary and submitted to the chairperson/ member secretary who will acknowledge the receipt.
- All safety reports will be addressed to the chairperson/member secretary and he/she will put up the same for review by the board members. If an adverse event poses serious and unnecessary risk to study subject safety, the chairperson or the members as a whole may immediately suspend the study.
- In the event of a death of a study subject, the investigator must submit the report immediately suspends the study.

17.1 NON-SITE SAE REVIEW:

- Principal Investigator or Designate Study Team should report Off Site SAEs to IEC on time
- If Principal Investigator notices any particular trend in SAEs should be informed to IEC.

Off-site SAEs (PSUR): **(Refer "Annexure O" for Non-site SAE review)**

- Member Secretary shall file the PSUR/Line listings submitted by PI as a detailed review of the same is out of the scope of IEC
- It is the PI's responsibility to review the listings in detail and report if a trend is observed and communicate the same to Member Secretary
- The offsite SAEs are received and one copy is acknowledged and returned back to PI.
- If any queries are raised by the IEC Member Secretary shall write to PI (email or letters as applicable) or else the Offsite SAEs are filed in the respective project files.

Depending on the trend observed by the PI, if appropriate, IEC shall take required action.

- Direct the PI to inform participants already enrolled in the study about the SAE and if required re-consent these patients.
- Request additional details or recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- Suspend enrolment of new research participants;
- Suspend the study till amendments requested for by the IEC are accepted
- Suspend the study till additional information is obtained;
- Suspend the study till review is completed
- Terminate the study

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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18. DOCUMENT LIST TO BE SUBMITTED TO THE SHEC

For a thorough and complete review, all research proposals with the following documents.

1. Name of the applicant with designation and curriculum vitae.
2. Name of the institute/ hospital/ field area where study will be conducted.
3. The protocol which should include the following-
   - Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
   - Inclusion/ exclusion criteria for entry of subjects in the study.
   - Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures, if any.
   - A description of plans to withdraw or withhold standard therapies in the course of research.
   - The plans for statistical analysis of the study.
   - Safety of proposed intervention and any drug or vaccine to be tested including result of relevant laboratory and animal research.
   - For research carrying more than minimal risk an account of plans to provide medical therapy for such risk or injury or toxicity due to dosage should be included
   - Proposed compensation and reimbursement of incidental expenses
   - Storage and maintenance of all data collected during the trial.
4. Investigator's brochure and other available safety information.
5. Written informed consent form (s) in English and vernacular languages and consent form updates that the investigator proposes for use in the trial, procedure for seeking and obtaining informed consent with sample of patient information sheet.
6. Required ICF in English, Hindi and also required back translation.
7. Information about payment and compensation available to subjects, if not covered in protocol or in informed consent sheet. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants, a description of the arrangements for indemnity, if applicable (in study- related injuries), a description of the arrangements for insurance coverage for research participants, if applicable.
8. In case children's are to be enrolled in a clinical trial, the assent form (informed consent form for children/ minor).
9. Subject recruitment procedure (e.g. advertisements), if applicable
10. Any other written information to be provided to subjects.
11. Insurance policy statement/ compensation for any physical or mental injury.

Reviewed By (Sign):

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Approved By (Sign):

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12. Clinical Trial Agreement (CTA will be tripartite with signature of Head of the institution or his designee, Principal investigator and the sponsor/representative of sponsor.
13. Confidentiality agreement and clinical trial agreement along with letter of indemnity including agreement to comply with national and international GCP protocols for clinical trial, if not covered in protocol or other clinical trial agreement.
14. Details of funding agency or sponsors and fund allocation for the proposed work.
15. DCGI's approval and other regulatory clearance certificate
16. An agreement to report only serious events (SAE) to SHEC
17. Any other information relevant to the study
18. Registration on Clinical Trials Registry-India (CTRI)

19. **MONITORING/AUDIT OF TRIALS:**

SHEC will monitor the following-

- Right, safety and wellbeing of trial subjects to be maintained throughout the trial.
- Consent process for all the subjects. All subjects should signed updated version of ICF.
- AE and SAE management for trial subjects by the Investigator and site, also assess the causality of SAE
- To assure the compliance to be applied for the trial as per guidelines and procedures.
- To identify and apply any changes or some improvement needed, if takes place.
- Periodic review of trial for risk evaluation and adverse event monitoring.

(Refer "Annexure I" for EC monitoring/ Inspection Method)

20. **SELF ASSESSMENT:**

- SHEC will conduct self-assessment on periodically at least once a year and if EC found any corrective and preventive actions are require, they shall be implemented accordingly.

Refer Annexure "J" for the self-assessment of EC.

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 SHEC 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. Nupur Kasliwal
Member Secretary
Somani Hospital Ethics Committee

Dr. Vishnu Bhutia
Chairman
Somani Hospital Ethics Committee

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • MEMBER SECRETARY

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • CHAIRMAN

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Somani Hospital, 27, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019
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Somani Hospital Ethics Committee

ANNEXURE -A

FINANCIAL DECLARATION OF PAYMENT RECEIVED AND DISBURSED

Procedure to maintain financial records:

- All payment received as Institutional Ethics Committee submission/Amendment/Annual review fee are maintained under "Somani Hospital".
- All payment cheque /DD will submit to account department of the "Somani Hospital".
- All expenditure of IEC are managed through payment received as fee including EC supporting staff salary, meeting arrangement cost, Travel arrangement to chairperson and all other members, Stationary charges, Cupboard, Electricity and telephone bills infrastructure requirement including Computer, Xerox, Scanner, Ethics Committee Member Training arrangement etc.
- All financial payments received and disbursed shall be reviewed at end of every financial year.
- All financial communications are liable under Institute's internal routine account audit.

FEE DETAILS:

(I) Processing fee for project sponsored by pharmaceutical company will be 1,00,000/- (One Lakhs Only) and the extra processing fee of Rs. 25,000/- (Twenty Five Thousand only) for expedited review.

(II) Processing fee for project sponsored by Govt. agencies/ Investigator initiated trials/ Research scholars/ will be Rs. 30,000/- (Thirty Thousand only) and the extra processing fee of Rs. 15,000/- (Fifteen thousand only) will be charged for expedited review.

(III) Processing fee for **any amendment** in project related documents will be Rs. 40,000/- (Fourty thousand only) and the extra processing fee of Rs. 15,000/- (Fifteen thousand only) for expedited review.

(IV) Processing fee for **annual review** & review of protocol, IB and ICF for ongoing project will be Rs. 20,000/- (Twenty thousand only).

(V) Processing fee for **SAE review** will be Rs. 40,000/- (Fourty Thousand only)

(VI) The fee is to be paid by Cheque/ DD/NEFT/RTGS in favor of "**Somani Hospital**" payable at Jaipur.
Bank Name- State Bank of India, Mahesh Nagar, Jaipur-302019
IFSC Code: SBIN0017635
A/c No.: 33762519810
PAN No. – AAEPR2435C
GST charges will be extra. TDS will be included.

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

ANNEXURE B

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER LIST

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail I.D. and mailing address	Designation / Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1.	Dr. Vishnu Bhutia	M.D. (Gen. Medicine)	Sr. Consultant, Internal Medicine, Agrasen Hospital, Jaipur-302019, Rajasthan	Mob No. +91-9829088172 Fax No. 0141-2504110 Email: vishnubhutia@yahoo.co.in Address: 76, Devi Nagar, Agrasen Hospital, New Sanganer Road, Jaipur-302019, Rajasthan	Chairman	No
2.	Dr. Nupur Kasliwal	D.G.O. (Obs &Gynae)	Consultant Gynaecologist, Somani Hospital, Jaipur	Mob No. +09351767878 Fax No. 0141-2504110 Email: nupur_kasliwal@yahoo.co.in Address: 45-46, Shiv Marg, Guru Jhambeshwar Nagar A, Block E, Vaishali Nagar, Jaipur-302021, Rajasthan	Member Secretary	Yes
3.	Dr. Diwanshu Khatana	MBBS, M.D. (Gen.Medicine)	Consultant Physician, Somani Hospital, Jaipur-302019, Raj.	Mob – +91-9799358888 Fax No. 0141-2504110 Email– Address: 65, Bhagwati Nagar 1st, Kartarpura, Lal Kothi, Gandhi Nagar, Jaipur-302015, Rajasthan	Clinician	Yes

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

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4.	Dr. Sudhendra Sharma	MD(Gen. Medicine)	Consultant Physician in ECHS, 12, Khatipura Rd, Lakshmi Nagar, Jaipur, Rajasthan 302006	Mob no. – 09829019676 Fax no. – 0141-2504110 Email- drsudhendrasharma@gmail.com Address: 293, C-Block, Devi Chiranjivi Colony, Surya Nagar, Gopal Pura Mode, Jaipur, Rajasthan 302015	Clinician	No
5.	Dr. Lalit Mohan Sharma	MD(Medical Oncology)	Sr. Medical Oncologist, Mahatma Gandhi Medical College & Hospital, Jaipur	Mob no.- 09928602244 Fax no. – 0141-2504110 Email- drlalit2003@gmail.com Address: 67/166, near Bank of Maharashtra, Pratap Nagar, Sector 6, Sanganer, Jaipur, Rajasthan 302015	Clinician	No
6.	Dr. Manohar Lal Bhatia	MD (Pharmacology)	Director of Prithasavi Hospital, Jagatpura, Jaipur-302017, Raj.	Mob No. +919530202223 Fax No. 0141-2504110 Email – prithasavi@gmail.com Address: 215, Gali No. 1, Mahadev Nagar, SKIT College Road, Jagatpura, Jaipur-302017, Rajasthan	Basic Medical Scientist	No
7.	Mr. Chandra Shekhar	L.L.B.	Advocate, Rajasthan High Court, Jaipur	Mob No. 09828016624 Fax No. 0141-2504110 Email– adv.chshekhar@yahoo.co.in Address: 97 Shanti Nagar, DCM Ajmer Road, Jaipur, Rajasthan	Legal Expert	No
8.	Dr. Ashok Kumar Peepliwal	Ph. D; L.L.B.	Associate Professor, IIHMR University, Jaipur	Mob No. – 09799995927 Fax No. 0141-2504110 Email- apeepliwal@gmail.com Address: Plot No. 13, Mauzi Colony, Pratapnagar, Sector-8, Sanganer Jaipur-302033, Rajasthan	Legal Expert	No

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

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E-mail : ecsomanihospital@gmail.com • Web.: www.somanihealthcare.com

9.	Mrs. Reena Gupta	Master in Social Work (MSW)	Social Scientist in Apex Hospital Ethics Committee, Jaipur	Mob No. – 09887521213 Fax No. 0141-2504110 Email– rajesh.vineet@gmail.com Address: 72/103, Shipra Path. Patel Marg, Mansarovar, Jaipur-302020, Rajsthan	Social Scientist	No
10.	Mrs. Abha Maheshwari	BA (English)	Coordinator-Mission Heart Operation (NGO), Jaipur	Mob NO. 09314631353, Fax No. 0141-2504110 Email- abhamaheshwari@gmail.com Address: 32, Shri Gopal Nagar, Gopal pura Bypass, Jaipur-302019, Rajasthan	Member	No
11.	Mrs. Reshma Dugar	M.A. (English)	Professor, Kisan Law College, Banipark, Jaipur	Mob no. – 09829034513, Fax No. 0141-2504110 Email– resdugar@gmail.com Address: D-253-B, Devi Marg, Banipark, Jaipur-302016, Rajasthan	Lay Person	No

Dr. Nupur Kasliwal
Member Secretary,
Somani Hospital Ethics Committee

Dr. Vishnu Bhutia
Chairman
Somani Hospital Ethics Committee

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

ANNEXURE - C

CONFIDENTIALITY AND CONFLICT OF AGREEMENT FORM FOR SHEC MEMBERS

In recognition of the fact that I _____ herein referred to as the Undersigned has been appointed as a member of the Somani Hospital Ethics Committee (SHEC) would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a human and ethical manner with the highest standards of care according to the applied national local regulations institutional policies and guidelines.

Whereas the appointment of the undersigned as a member of the SHEC is based on individual merits and not as an advocate or representative of a home province/territory/community norms the delegate of any organization or private interest.

Whereas, the fundamental duty of an SHEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

Whereas the SHEC must meet the highest ethical standards. In order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects.

The undersigned as a member of the SHEC is expected to meet the same high standards of ethical behavior

This Agreement thus encompasses any information deemed Confidential or Proprietary to the Undersigned in conjunction with the duties as a member of the SHEC. Any written information provided to the Undersigned that is of a Confidential Proprietary or Privileged nature shall be identified accordingly.

As such the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for Contemplated purposes shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the SHEC.

The Undersigned agrees not to disclose or utilize directly or indirectly any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore the Undersigned confirms that my performance of this agreement is consistent with the Institute s policies and any contractual obligations they may have to third parties.

CONFLICT OF INTEREST

It has been recognized that the potential for conflict of interest will always exist but faith in the SHEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the SHEC, 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 SHEC.

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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The undersigned will immediately disclose to the Chairperson of the SHEC 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.

If an applicant submitting a protocol believes that a SHEC 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 Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the SHEC member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the SHEC review or approval except to provide information requested by the Committee.

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

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

In the course of my activities as the SHEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information").I agree to tack reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act , not to disclose the Confidential Information to any person ; not to use the Confidential Information for any purpose outside the Committee mandate, and in particular in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not committee not to count me toward a quorum for consensus or voting. I.....have read and I accept the aforementioned terms and conditions as explained in this Agreement.

UNDERSIGNED SIGNATURE: **DATE:**

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

Address

Somani Hospital, 277, Shri Gopal Nagar, 80 Ft. Road, Gopalpura Byepass, Jaipur - 302019

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Somani Hospital Ethics Committee

ANNEXURE – D

JOINING CONSENT

To,
The Chairman,
Somani Hospital Ethics Committee,
277, Shri Gopal Nagar, 80 Feet Road,
Gopalpura Bypass, Jaipur-302019

Sub: - Consent to be a member of IEC
Sir,

- I accept the invitation to become a Member of Somani Hospital Ethics Committee, Jaipur.
- I shall regularly participate in the committee meeting to review and give my unbiased opinion regarding the scientific and ethical issues.
- I shall be willing to publicize my full name, profession and affiliation,
- I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC.
- I shall not keep any literature of study related document 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 any other than project personnel.
- I shall work independently as a member; no conflict of interest will be there for giving opinion to any study, in case of conflict of interest I will not vote for that study.

Thanking You

You're sincerely,

Name of Member.....
Designation/Role.....
Address: .....
Contact No.....

Acknowledgment
We confirm receipt of the above mention letter

Received By: .....

Designation:

Reviewed By (Sign): .....

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign): .....

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

ANNEXURE – E

EXTENSION CONSENT

To,
The Chairman,
Somani Hospital Ethics Committee,
277, Shri Gopal Nagar, 80 Feet Road,
Gopalpura Bypass, Jaipur-302019

Sub: - Consent for extension of membership of IEC

Sir,

- I agree to extend my Membership of Somani Hospital Ethics Committee, Jaipur.
- I shall regularly participate in the committee meeting to review and give my unbiased opinion regarding the scientific and ethical issues.
- I shall be willing to publicize my full name, profession and affiliation,
- I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC.
- I shall not keep any literature of study related document 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 any other than project personnel.
- I shall work independently as a member; no conflict of interest will be there for giving opinion to any study, in case of conflict of interest I will not vote for that study.

Thanking You

You're sincerely,

Name of Member.....
Designation/Role.....
Address: .....
Contact No.....

Acknowledgment
We confirm receipt of the above mention letter

Received By: .....

Designation:

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

ANNEXURE – F

SOMANI HOSPITAL ETHICS COMMITTEE, JAIPUR

TRAINING RECORD

Training Topic:

Trainer Name:

Training Date:

Training Session Time:

S.N.	Name	Designation	Trainee Signature
1.	Dr. Vishnu Bhutia	Chairman	
2.	Dr. Nupur Kasliwal	Member Secretary	
3.	Dr. Diwanshu Khatana	Clinician	
4.	Dr. Lalit Mohan Sharma	Clinician	
5.	Dr. Sudhendra Sharma	Clinician	
6.	Dr. Manohar Lal Bhatia	Basic Medical Scientist (Pharmacologist)	
7.	Mr. Chandra Shekhar	Legal Expert	
8.	Dr. Ashok Kumar Peepliwal	Legal Expert	
9.	Ms. Reena Gupta	Social Scientist	
10.	Ms. Abha Maheshwari	Member	
11.	Ms. Reshma Dugar	Lay Person	

Signature of Chairman/Member Secretary

Somani Hospital Ethics Committee

Trainer Signature

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

ANNEXURE – G

CONFIDENTIALITY DOCUMENT FORM FOR INDEPENDENT CONSULTANTS

I .....(name and designation) as a non-member of SHEC understand that the copy (ies) given to me by the SHEC is (are) confidential. I shall use the information only for the indicated purpose as described to the SHEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the SHEC.

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

Signature.....

Name.....

Date.....

Consultant/Specialty.....

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • MEMBER SECRETARY

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • CHAIRMAN

Address

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Somani Hospital Ethics Committee

ANNEXURE – H

INVITATION TO ATTEND A MEETING AS INDEPENDENT CONSULTANT

To,

.....

.....

.....

Subject: Invitation to attend Institutional Ethics Committee meeting.

Sir/Madam,

The Chairman SHEC has nominated you as an Independent consultant/observer to evaluate a research protocol submitted to the Somani Hospital Ethics Committee for approval.

You are requested to attend the meeting of IEC on ..... at ..... and to provide written opinion regarding the assigned research proposal (Protocol No ..... and title of project.....). You will not have any voting right during the meeting and you will have to sign confidentiality document, which is enclosed for your kind perusal.

Kindly note that all the documents submitted to you are confidential. These should not be disclosed to anyone and should be returned to the Somani Hospital Ethics Committee after the meeting.

Yours faithfully,

Signature of the Chairman/Member Secretary..... Date.....

Name .....

Enclosures:

1. Research protocol
2. Confidentiality document

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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E-mail : ecsomanihospital@gmail.com • Web.: www.somanihealthcare.com

Somani Hospital Ethics Committee

ANNEXURE-I

EC MONITORING / INSPECTION METHODS

Somani Hospital Ethics Committee
277, Shri Gopal Nagar, 80 Feet Road, Gopalpura Byepass, Jaipur-302019, Rajasthan.
Email ID: ecsomanihospital@gmail.com
Phone No- 0141- 2504996: Fax No- 0141- 2504110

EC will monitor/inspect time to time Clinical Research Department of Somani Hospital at least once in a year or once in study duration (whichever earlier) to take the overview of ongoing clinical trials.
Monitoring/Inspection of EC is for the right, safety, well- being of trial subjects, process of trial should be as per GCP guideline, New Drugs and Clinical Trials Rules, 2019and other applicable regulatory guidelines.

EC will require the following details from Principal Investigator/Site:
Checklist for Monitoring/Inspection of ongoing trials.
(This list not all inclusive; item may be added &/or deleted as per the Study/Site/Investigator)

I.	General Information		
1.	Name, address and contact details of the clinical trial site		
2.	Date of Monitoring		
3.	Date of Last Monitoring		
4.	Monitoring Team Members:		
5.	Personnel present during Monitoring (with name and role/designation)	Name & Designation	Signature
		1.	
		2.	
		3.	
		4.	
6.	Name & address of the Study Sponsor/CRO/SMO		
7.	Protocol Title		
8.	Protocol Number Version/date Protocol amendments, if any		
9.	Investigational Product/Device		
10.	Stage of study: (Mark the relevant)	(A) Before Trial Commencement (B) During Conduct of the trial (C) After Completion of Trial	

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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11.	Type of Inspection (Mark the relevant)	A. Surveillance	B. For Cause

S. No.	Items	YES	NO	NA	Remark
II. Administrative Aspects:					
1.	Clinical trial NOC from O/o DCGI (Note: mention along with Protocol no., Ver., date)				
2.	NOC for subsequent protocol amendments, if any from O/o DCGI				
3.	Ethics Committee approval date (Note: mention along with Protocol no., Ver., date)				
4.	Whether valid financial agreement between the Sponsor, Investigator & Institution available.				
5.	Whether liability of involved parties (Investigator, Sponsor and Institution) clearly agreed.				
6.	Is the valid clinical trial Insurance available? (date of expiry)				
7.	Site Initiation date				
8.	Date of screening of first subject,				
9.	Date of signing ICF by the first subject				
10	Date of Last Patient-Last Follow-Up (if applicable)				
11.	Whether SOP for various activities are established and documented.				
12.	Verify, whether the hospital/institute/site has adequate emergency care facilities to handle emergency situation.				
III Organization & Personnel					
1.	Assure that signed & dated, Curriculum Vitae is available for the Investigator, Sub Investigator /Co-Investigator/Delegated site staff				
2.	Confirm the educational qualification of the Investigator with registration by Medical Council of State/India.				
3.	Confirm the GCP, Schedule Y and protocol specific training of Investigator, Sub-Investigator/Co-Investigator and its team.				

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR

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4.	Determine whether authority for conducting various clinical trial activities were delegated properly by Investigator to competent personnel (obtain the list of personnel and duty delegation log).				
5.	Check whether the person whom the authority is delegated is adequately qualified and trained for the activity/activities assigned.				
IV Conduct of Trial					
A.	**Screening of subjects:**				
1.	Check and review the informed consent for the screening of the subjects.				
2.	Check site screening log & enrolment log and obtain authenticated copy.				
3.	Check whether the subjects are meeting the inclusion/exclusion criteria as per the approved protocol w.r.t review of source documents & CRF.				
B. Subject record and Informed consent:					
1.	Whether ICF have all the elements enlisted in Appendix V of Schedule Y.				
2.	Whether ICF is approved by Ethics Committee prior to consent process.				
3.	Whether ICF has been obtained from each subject prior to participation of the subject in the study.				
4.	Whether signature/thumb impression of the subjects/legal representative have been affixed with date.				
5.	Whether in case of illiterate subjects or illiterate representative of a subject, there are signature and details of an impartial witness.				
6.	Have witness/ signature being personally dated.				
7.	Has the dated signature of the designated person for administering informed consent (IC) been affixed?				
8.	Is the designated person for administering IC medically qualified?				
9.	If IC has been administered by a designated person who is not medically qualified, is there evidence that subject's queries of a medical nature were				

Reviewed By (Sign):

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SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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	answered by a medically qualified person or the investigator?					
10.	Is the completed ICF signed and dated by the investigator?					
11.	Check weather re-consenting is done for changes in ICF, if any.					
12.	Is EC details with contact number share to Subject/LAR/Witness					
B.1	**Audio-Visual recording of Informed Consent Process(For 'vulnerable population' in 'New Chemical Entities (NCEs) clinical trial' only & Anti HIV & Anti-Leprosy patients only Audio recording)** (Verify as per GSR 611(E) dated 31.07.2015)				Applicable	Not applicable
1.	Whether audio-visual recording is performed for all subjects, independently.					
2.	Is audio-visual recording conducted in a room conducive to recording of disturbance free audio and video of the consent process? (image is recognizable and the audio is clearly audible)					
3.	Check whether the recording of informed consent process is preserved safely.					
V. Investigational Product						
1.	Review individual subject record to verify the correct dose administration with respect to dose, frequency, route of administration					
2.	Investigational drug dispensed/administrated by qualified and authorized personnel?					
3.	Determine whether adequate record of quantity of test drug received, dispensed is maintained. (Check the test drug reconciliation and verify the leftover drug or balance on the day of inspection).					
4.	Storage condition/monitoring method are as per protocol/recommendation?					
5.	Whether trial medication are maintained in secured manner with controlled access;					
6.	Have un-used trial medications been returned to the sponsor or disposed of according to protocol?					
7.	Are the drugs dispensing records being maintained properly?					
8.	Whether the records for reconciliation of all IP's are maintained?					

Reviewed By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

9.	Are electronic or hand-written temperature logs available for the storage area of the investigational products?				
10.	Verify that investigation product is appropriately labeled. (For clinical trial use only).				
VII. Pathology Laboratory (for Screening/ Assessment)					
1.	Name and address of the clinical laboratory used in the study. (Local and Outside).				
2.	Whether financial & Confidentiality agreement with Investigator and concerned laboratory (ies) in place.				
3.	Is investigator/Sponsor verified the accreditation status and adequacy of the facilities to perform the specified tests as per protocol.				
4.	Verify whether the SOP for sample preparation, handling and transportation is available. Verify the appropriateness of the SOP.				
C. Source Documents and Case Record Form					
1	Verify condition, completeness, legibility, accessibility of the investigators source data file. (source data includes study subject's files, recording from automated instruments, tracings, X-ray and other films, laboratory notes, photograph negatives, magnetic media, hospital records, clinical and office charts, subject's diaries, evaluation checklists and pharmacy dispensing records)				
2	Determine whether safety/ efficacy end point data(Clinical, laboratory examination results) were collected and reported in accordance with the protocol				
3	Does medical record mentions subject ID/ name /hospital registration number / and indication that subjects are participating in a clinical trial.				
4	Compare the source document with CRF and determine whether source data have been correctly transcribed in CRF;				
5	Verify the drop-outs and reason for drop-out of subject is appropriately recorded.				
6	Whether the withdrawal of subject from the study is recorded and appropriately justified in				

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE MEMBER SECRETARY JAIPUR-19

SOMANI HOSPITAL ETHICS COMMITTEE CHAIRMAN JAIPUR-19

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Somani Hospital Ethics Committee

	accordance with approved protocol.				
7	Verify whether Standard Operating Procedure of handling of Serious Adverse Event occurred in clinical trial is available.				
8	Verify whether all SAE's have been reported to the sponsor, EC and Licensing authority as per the timelines in accordance with NDCTR-2019 (Verify as per GSR 53(E) dated 30.01.2013 & GSR 889 (E) dated 12.12.14 effective from 12.06.2015)				
9	Verify Whether SOP for medical care during serious adverse event is available or not.				
10	Verify whether adequate medical care have been given to the subject especially in the event of inter current illness, adverse events including abnormal lab parameters;				
11	Verify whether all study related activities are performed at site approved by O/o DCGI.				
VIII. Record keeping and data handling					
1.	Is adequate space available for document retention?				
2.	Whether documents are maintained properly and for the period as specified?				
3.	Whether necessary measures have been taken to prevent accidental or premature destruction.				
4.	Whether the archival access controlled or restricted to authorized personnel.				
5.	Weather SOP available to document all steps in data management in order to allow step by step retrospective assessment of data quality and study performance.				
6.	Whether corrections in documents carry the date and initials of Investigators and authorized person.				

Name and Designation of Monitoring Person(s): 1. 2. 3.	Sign & Date:
Reviewed By: Chairman/Member Secretary Name:	Sign & Date:

Reviewed By (Sign):

Approved By (Sign):

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • MEMBER SECRETARY

SOMANI HOSPITAL ETHICS COMMITTEE • JAIPUR-19 • CHAIRMAN

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