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. Rakesh Chandra Andley, Chairman,** Medical Officer, Eternal Heart Care Center And Research Institute, Jaipur
2. **Dr. Rajkumari Somani, Member Secretary,** Director, Consultant Gynecologist, Somani Hospital & Research Center, Jaipur
3. **Dr. Vishnu Bhutia, Member(Clinician),** Sr.Consultant, Internal Medicine, Agrasen Hospital, Jaipur
4. **Dr. Manohar Lal Bhatia, Member (Pharmacologist),** Director of Prithasavi Hospital, Jagatpura, Jaipur-302017, Raj.
5. **Mr. Chandra Shekhar, Legal Expert,** Advocate, Rajasthan High court, Jaipur
6. **Mr. Niranjan Lal Sharma, Legal Expert,** Advocate, Rajasthan High Court, Jaipur
7. **Dr. Asha Hingar, Social Member,** Former Professor, Dept. Of Psychology, Rajasthan University, Jaipur
8. **Dr. N.K. Gurbani, Scientific Member (Biomedical Scientist & Pharmacologist),** Former Head, Public Health Training Institute, Jaipur
9. **Mrs. Abha Maheshwari, Scientific Member,** Mission Heart Operation (A Non-Government organization) Jaipur
10. **Mr. Satya Narayan Modani, Member (Lay Person),** Syam Nagar, Sodala, Jaipur
11. **Mrs. Tanvi Gupta, Member (Lay Person)** G-2, 31 & 32, Lane No. 2, Lord Krishna Residency, R.R. Nagar, Patrakar Colony, Mansarover, Jaipur-302020, Rajasthan

1. Constitution & Functions

A. SoMex Research & Health Ethics Committee is authorized under SoMex Research & Health Pvt. Ltd. Register under the company Act 1956. Corporate Identity no. of company U2432RJ2007PTC025278.

B. 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.

C. 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.

277, IInd Floor, Shri Gopal Nagar, 80 feet Road, Gopalpura Bye Pass, Jaipur-302019
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ETHICS COMMITTEE
SOMEX RESEARCH & HEALTH ETHICS COMMITTEE
JAIPUR-302 019

SoMex Research & Health Ethics Committee

- This Committee will examine and approve or disapprove submitted research projects as per their scientific and ethical aspects.
- It will be the responsibility of 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 Thirteen (13) 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 01 weeks prior to propose EC meeting date.

2. Meeting of Ethics Committee

- The meeting of Ethics committee will be convened every 03 months regularly, preferably on the Friday/Saturday of the month; in case there is proposal before EC for review, EC meeting can be called earlier with a prior sufficient period notice to all EC members.
- If this is a government holiday or meeting not being convened on proposed meeting date the EC will meet on the subsequent Friday/ Saturday.
- The Chairman is empowered to call the expedite meeting of Ethics Committee at a notice of seven days besides the regular meeting.
- Members of the Ethics Committee are appointed by directors of the organization and member will be appointed for three years also willing to work according to Schedule-Y, ICH-GCP Guidelines and willing to work according to rules as and when amended.
- Quorum of EC minimum of 5 members with the following representations.
  - ❖ Basic medical scientist (preferably one pharmacologist)
  - ❖ Clinician (Post Graduate)
  - ❖ Legal expert
  - ❖ Social scientist or representative of nongovernmental voluntary agency or philosopher or ethics or theologian or a similar person.
  - ❖ Lay person from community.
- New and existing members are trained by Member Secretary regarding ICH-GCP, Schedule-Y guidelines as well as new clinical trial to be discussed.

a. Independent Ethics Committee members of SoMex Research & Health Ethics Committee are qualified technical members.
b. Committee members are conversant with Drug and Cosmetic rules 1945 (3rd amendment).
c. Committee members are trained and practices in accordance with the ICMR 'good clinical guidelines' ensuring protection of rights, safety and well being of human subjects involve in clinical research.
d. They have experienced in Clinical Research and have been in such committees for the last several years.

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e. Committee members regularly organizing scientific meeting where clinical trials are discussed.
f. Every member proactively participates in annual workshops.
g. A new member will be inducted 1 month prior and will be requested to be an 'observer' for the first board meeting.
h. An introductory training will be imparted by the Member Secretary
- SOP Version 7.0 dated 13 April 2019 _SOPs_ Independent Ethics Committee of SoMex Research & Health Ethics Committee SOP

i. The IEC members will be encouraged to receive ongoing training by attending workshop at least once every year.
j. The IEC will conduct workshops from time to time to impart training to the IEC members and Institutional faculty members.
k. The training programmes should be scheduled and spread over the year.

- 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.

3. Procedure for resignation, replacement or removal of members

Voluntary written submission of resignation by any member. Replacement or removal of member by director of organization, after consulting and approval of chairman of Ethics Committee.

4. 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 all available clinical data of the trial drug with adequate bibiology graphy.
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

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be submitted later in cases where the permission to conducted the trial has been applied for and approval is awaited from the DCGI.

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 (IInd 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 provide to subjects)
L. The EC may request additional information than outlined in the ICF to be give 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.
M. Other all documents related to study.

5. Processing Fee

(I) **Processing fee** for project sponsored by pharmaceutical company will be Rs. 50000/- Rs (Fifty Thousand Only) and the extra processing fee of Rs. 20000/- (Twenty Thousand only) will be charged if a special 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. 20000/- (Twenty Thousand only) and the extra processing fee of Rs. 10000/- (Ten thousand only) 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 Rs. 25000/- (Twenty Five Thousand only) and the extra processing fee of Rs. 10000/- (Ten thousand only) will be charged if a special meeting is to be called for the processing of the project apart from the regular meeting.

(IV) Annual review fee for ongoing clinical trials will be 10000/-Rs (Ten thousand only).

(V) The fee is to be paid by cheque/DD in favour of "SoMex Research & Health Pvt. Ltd." payable at Jaipur.
(PAN No. - AALCS4343Q: GSTIN No. 08AALCS4343Q1ZM).

6. Procedure of Vulnerable Population

The ethics committee will exercise particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study e.g., members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable disease, unemployed or impoverished persons, patients in emergency situation, ethic minority groups, homeless persons, nomads, refugees, minors or other incapable of personally giving consent.

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7. Vulnerable Populations and Informed Consent

Persons who may not be able to make free and informed decisions about their participation in research or medical care are considered vulnerable
populations may be easily coerced or have limited freedom to choose. Persons identified as vulnerable have additional safeguards in the research informed consent process

Vulnerable Populations protected in regulation are:

a) Children and wards of the state
b) Prisoners
c) Pregnant Women and fetuses
d) Cognitively Impaired

Other accepted vulnerable populations are:

a) Non-English speaking persons
b) Illiterate persons
c) Financially impaired
d) Terminally Ill

8. Informed Consent & Prisoners

Prisoners, due to the lack of control of their circumstances are considered vulnerable DO NOT enroll prisoners unless you check with the IRB first. There MUST be a prisoner representative on the IRB if a prisoner is enrolled. If a person becomes a prisoner during a trial, notify the IRB immediately. Informed consent for a prisoner would state that participation will not be considered in parole consideration. Must state that risks for prisoner in this study same as for a non-prisoner. If a prisoner is treated in a research study and the IRB is not aware or does not have a prisoner advocate on the committee, federal regulatory bodies must be notified.

9. Informed Consent & Pregnant Women

Researchers should obtain informed consent from both the pregnant woman and the father. Consent of the father is not necessary if:

a) The purpose of the study is to meet the health needs of the mother.
b) The identity or whereabouts of the father cannot be reasonably ascertained
c) The father is not reasonably available.
d) The pregnancy is the result of rape.

NOTE: Research targeting pregnant women as subjects does not qualify for an exempt status.

10. Informed Consent in Fetal Research

Ex Utero Research Study: personnel may play no part in determination of fetal viability Many regulatory restrictions based upon viability of fetus. Mother and father must be legally competent and have given their informed consent. (Consent of Father may not be required). If anticipating this type of research, contact IRB or ORC during planning phases.

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11. Informed Consent & Cognitively Impaired

Persons with diagnosed cognitive impairment such as mental retardation, dementia, and coma, can participate in research. This type of research must specifically address how an individual's capacity to give informed consent will be determined. The signature of a legally authorized representative will be required Research with Cognitively Impaired subjects cannot be considered exempt by the IRB. Document carefully the enrollment of persons whose cognitive status is not outwardly obvious e.g. stroke patients, psychiatric patients or persons with speech or language disorders. If a person is enrolled in a study during a period of cognitive impairment and regains his ability to give consent – he must be re-consented.

12. Informed Consent & Illiterate Persons

An investigator may enroll individuals, who can speak and understand English, but cannot read or write. The potential subject must be able to place a written mark on the consent form. The subject must also be able to comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally, and be able to indicate approval or disapproval for study enrollment. Additional items to document:

A. What method was used to communicate the information about the study
B. Who was present during the Informed Consent Interview
C. The specific ways that the subject communicated agreement to study participation

13. 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.
- 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.

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- As per ICMR guidelines, the investigator in mandated to submitted 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.

14. Procedure on Disclosure of Financial Interests & Management of Conflicts of Interests:

However, Ethics Committee will also monitor financial interest and management of Principal Investigator in following standard way:

A. Definitions

Equity (Ownership) or Investment Interest
An investment in the research sponsor by the principal investigator, his or her spouse, registered domestic partner, or dependent children. *Note: an investment is any direct, indirect, or beneficial financial interest in a business entity including stocks, bonds, warrants, and options, including those held in margin or brokerage accounts.

B. Financial Interest

For the purposes of this policy, a financial interest in the sponsor of the research means:

A. An equity (ownership) or investment interest;
B. A position as director, officer, partner, trustee, employee of or any other management position;
C. Income from the sponsor, including consulting income, received by or promised to the principal investigator within 12 months prior to the time the award is made.
D. A gift of (fair market value), or multiple gifts promised (fair market value) or more.

C. Gift

For purposes of this policy, gift includes compensation, payment or other things of value received by a faculty member, student or staff of the SoMex Research & Health Ethics Committee, Jaipur, when functioning within the research project and scope of Ethics Committee roles and responsibilities. For purposes of this policy, examples of "gifts" include the following:
-Free food and meals

-Pens, notepads, tour bags, etc.

-Free or discounted items where the individual receiving the item is not providing a service of similar or greater value

-Samples that are not a part of a formal evaluation process and/or a University contract

- Payment to attend meetings and travel or other activities, when the individual or unit receiving the

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payment is not providing a service of equal or greater value. For purposes of this policy "gift" does not include reasonable honoraria, prizes or awards, payment of expenses to speakers who participate in an accredited educational meeting consistent with standards for commercial support developed by the relevant Pharmaceutical/ Sponsor or honoraria and other payments allowed for

those faculty and staff eligible to receive these payments as compensation for specific services.

D. Income

A payment received, including but not limited to any salary, wage, honorarium, reimbursement, dividend, or advance.

E. Private Sponsor

Non-governmental sponsor of research including private and/or publically held companies, foundations, professional associations and voluntary health organizations.

F. Travel Payments

As defined under, include advances and reimbursements for travel and related expenses, including lodging and meals.

A. Travel payments may not be classified as gifts or as income, depending on the circumstances. **B.** Travel payments are gifts if you did not provided services which were equal to or greater in value than the payments received.

C. Travel payments are income if the principal investigator provided services which were equal to or greater in value than the payments received. When reporting travel payments as income, the principal investigator must describe the services he or she provided in exchange for the payment.

15. Policy

A. Disclosure

1. All persons employed or empanelled for SoMex Research & Health Ethics Committee, Jaipur, who have principal responsibility for a research project funded or supported, in whole or in part, by a contract or grant from a nongovernmental entity, must disclose any Financial Interest in the sponsor of research.
2. Disclosure statements must be filed:
    a) Before final acceptance of such a contract, grant, or gift
    b) When funding is renewed.

B. Review of Disclosures

In the case of a disclosed Financial Interest, the disclosure statement and the research project must be reviewed by the Independent SoMex Research & Health Ethics Committee, Jaipur. The committee makes a recommendation to the Director of SoMex Research & Health Pvt. Ltd., Jaipur, and provide a course of action.

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C Public Access to Information

Disclosure statements are subject to public inspection, Under RTI of Gov. of India.

E Chairman Ethics Committee

Chairman must disqualify research proposals for projects which are funded in whole or in part by a private sponsor in which Principal Investigator or team members have a Financial Interest.

16. Archival of documents

I. Documentation and Archival

All documentation and communication of IRB will be dated, filed and archived in a secured place. The person who is authorized by the chairperson will have access to the various documents. The documents will be archived for a minimum period of 5 (Five) years following the completion of the study.

Documents that will be filed and archived include but are not limited to.

a. The constitution, written standard operating procedures of IRB and regular (half – yearly) reports
b. The Curriculum Vitae of all committee members
c. A record of all income and expenses of IRB, including allowances and reimbursements made to the secretariat and committee members
d. The published guidelines for submission established by IRB
e. The agenda of the committee meetings
f. The minutes of the committee meetings
g. One copy of all materials submitted by an applicant
h. The correspondence by IRB members with applicants or concerned parties regarding application, decision and follow-up.
i. A copy of the decision and may advice or requirements sent to an applicant
j. All written documentations received during the follow – up
k. A notification of the completion, pre-mature suspension or pre- mature termination of a study.
l. Final summary or final report of the study

Record keeping and Archiving

a. The constitution and composition of the ethics Committee.
b. The Curriculum vitae of all the committee members.
c. Standard Operating Procedures followed by the committee.
d. National and international guidelines
e. Copies of the Protocol, data collection formats, Case Report Forms, investigational brochures etc. submitted for review.
f. All correspondence with committee members and investigators regarding application decision and follow up.
g. Agenda of all ethics committee meetings.
h. Minutes of all ethics committee meeting with signature of the Chairperson

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i. Copies of decisions communicated to the applicants.
j. Record of all notification issued for premature termination of a study with a summary of the reasons.
k. Final report of the study including microfilms, Compact Disks and/ or Video-recordings.
All records must be safely maintained after the completion/termination of the study for not less than 15 years from the date of completion or termination of the trial.

If required, Subject experts may be invited to offer their views. Further, based on the also be represented in the Ethics Committee as far as possible.

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 trails are being done in a most ethical ways and the patients are preferred over society and science.

Rajkumari

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

MEMBER SECRETARY
ETHICS COMMITTEE
SOMEX RESEARCH & HEALTH ETHICS COMMITTEE

Rakesh

Dr. Rakesh Chandra Andley
Chairman
SoMex Research & Health Ethics Committee

CHAIRMAN
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ANEXURE I

Joining Consent

To,
Chairman,
SoMex Research & Health Ethics Committee,
227, IInd Floor, Shri Gopal Nagar,
80 Feet Road, Gopalpura Bypass,
Jaipur-302019

Sub:- Consent to be a Member of EC

Sir,

- I accept the invitation to become a Member of SoMex Research & Health Ethics Committee, Somani Hospital Campus, 227, 2nd Floor, Shri Gopal Nagar, 80 Feet Road, Gopalpura Bypass, Jaipur-302019, Rajasthan, India.
- 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 EC.
- 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.

Thanking You
You're sincerely,

(Name and Address of EC Member)

Acknowledgment

We confirm receipt of the above mention letter

Received By:.....

Designation: Chairman, SoMex Research & Health Ethics Committee

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ANEXURE II

Resignation Letter

SoMex Research & Health Ethics Committee

To,
Chairman,
SoMex Research & Health Ethics Committee,
227, IInd Floor, Shri Gopal Nagar,
80 Feet Road, Gopal pura Byepass,
Jaipur-302019

Subject: Resignation consent to IEC

Sir,

Here, as per CDSCO requirement I am writing to my interest to resignation from post of Basic Medical Scientist (Pharmacologist) in SoMex Research & Health Ethics Committee, 227, IInd Floor, Shri Gopal Nagar, 80 Feet Road, Gopalpura Byepass, Jaipur-302019, I am glad to work with Ethics Committee and members of it. I reign due to my personal reasons and my assignments.

Thanking You,
Yours Sincerely,

(Name and Address of EC Member)

Acknowledgement:

I Confirm receipt of the above mention letter:

Received by:_____

Designation: Chairman, SoMex Research & Health Ethics Committee

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ANUXURE III

Training Log

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Phone: 0141-2504996, 3212996 Fax: 0141-2504110 E-mail: ec@somexresearch.com
Web: www.somexresearch.com

SCHEDULE Y, ICH-GCP GUIDELINES AND EC "STANDARD OPERATION PROCEDURE" TRAINING LOG			
Type of EC	Independent	Prepared By:	(Name with designation in SoMex EC)
Version Number	Version X.Y (English)	Reviewed By:	(Name with designation in SoMex EC)
Effective Date	dd mm yyyy	Date of Training	
S.No.	Trainee Name	Trainee Signature	

Trainer Name:

Trainer Signature:

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ANUXURE IV

SITE INSPECTION CHECKLIST

SoMex Research & Health Ethics Committee

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I.	General Information	
1.	Name and address of the clinical trial site	
2.	Date of Inspection	
3.	Inspection Team Members:	
4.	Personnel present during Inspection (with name and role/designation.)	
5.	Address & Contact details of Investigator site Coordinator	
6.	Name & address of the Sponsor	
7.	Protocol Title	
8.	Protocol Number Version/date Protocol amendments, if any	
9.	Investigational Product	
10.	Stage of study: (Mark the relevant)	(A) Before Trial Commencement (B) During Conduct of the trial (C) After Completion of Trial
11.	Type of Inspection:	Surveillance For Cause

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S.No.	Items	YES	NO	NA	Remark
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?				
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.				

277, IInd Floor, Shri Gopal Nagar, 80 feet Road, Gopalpura Bye Pass, Jaipur-302019
Phone : 0141-8104124996, 2504996 Fax : 0141-2504110
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MEMBER SECRETARY ETHICS COMMITTEE RESEARCH & HEALTH ETHICS COMMITTEE JAIPUR-302 019

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III Organisation & Personnel					
1.	Assure that signed & dated, Curriculum Vitae is available for the Investigator, Sub Investigator /Co-Investigator				
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.				
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 &/or CRF.				
B. Subject record and Informed consent:					
1.	Whether ICF have all the elements enlisted in Appendix V of Schedule Y.				

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2.	Whether ICF is approved by Ethics Committee prior to consent process.				
3.	Whether IC 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.(If applicable).				
7.	Have patient/witness signature been personally dated?				
8.	Has the dated signature of the designated person for administering informed consent (IC) been affixed?				
9.	Is the designated person for administering IC medically qualified?				
10.	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 answered by a medically qualified person or the investigator?				
11.	Is the completed ICF signed and dated by the investigator?				
12.	Check weather re-consenting is done for changes in ICF, if any.				

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13.	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)				
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?				
3.	Check whether the video recording is free from disturbance to ensure that the image is recognizable and the audio is clearly audible				
4.	Check whether the recording of informed consent process is preserved safely.				
V. Sponsor					
1.	Whether investigator maintain copies of all report submitted to the sponsor;				
2.	Whether all CRF were submitted to sponsor after completion of study;				
3.	Determine whether all dropout and reason thereof were reported to sponsor;				
4.	Determine the method and frequency of monitoring the progress of the study by the sponsor and corrective action by site.				
5.	Whether sponsor appointed a monitor with appropriate qualification and experience to monitor trial at the site.				

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6.	Whether a log of onsite monitoring visit is maintained at the site.				
7.	Is monitor submits visit report with deviations if any to the sponsor.				
8.	Whether sponsor performed an audit as a part of QA in order to independent and separate from routine monitoring of quality control function.				
9.	n case the investigator and sponsor agrees to prematurely terminate or suspend the study for any reason, whether it was promptly informed to study subjects, Ethics Committee and Licensing Authority.				
VI. Investigational Product					
1.	Review individual subject record to verify the correct dose administration with respect to dose, frequency, route of administration				
2.	Determine whether unqualified /unauthorised persons administered/dispensed the test drug				
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.	Determine whether storage condition/monitoring method are as per protocol/recommendation;				
5.	Whether trial medication are maintained in secured manner with controlled access;				

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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?				
9.	Are electronic or hand-written temperature logs available for the storage area of the investigational products?				
10.	Verify that investigation product is appropriately labelled. (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.				
VIII. Record keeping and data handling					
1.	Is adequate space available for document retention?				
2.	Determine whether documents are maintained properly and for the period as specified.				

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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.				

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