Standard Operating Procedures for Clinical Research (SMO SOP)

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Standard Operating Procedure (SOP) for Clinical Research

SMO SOP ; Version 01.

Prepared: Clinical Team of SSCR

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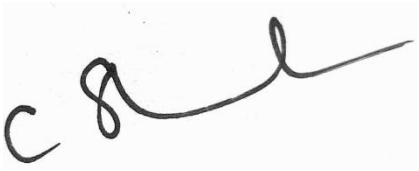

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Distribution List

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For reference of all investigators and clinical Study Team

Table of Contents

List of Abbreviations

- AE : Adverse Event
- CDSCO : Central Drugs Standard Control Organization
- COI : Conflict of Interest
- CTRI : Clinical Study Registry of India CRO Clinical Research Organization
- DCGI : Drug Controller General of India
- GCP : Good Clinical Practice
- GLP : Good Laboratory Practice
- ICD : Informed Consent Documents
- ICMR : Indian Council of Medical Research
- IEC : Institutional Ethics Committee
- IP : Investigational Product
- LAR : Legally Acceptable Representative
- PI : Principal Investigator
- SAE : Serious Adverse Event
- SOP : Standard Operating Procedures

Introduction to SS CLINI RESEARCH LLP (SSCR)

SS CLINI RESEARCH LLP (SSCR) registered under the Ministry of Corporate Affairs Government of India, is the Site Management Organization (SMO) that undertakes clinical study and other types of clinical research related work in clinical site, subjected to approval of regulatory authorities, approval of Institutional Ethics Committee (IEC) and compliance to competent authority guidelines on clinical research. The guidelines for clinical research include, Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017; New Drugs and Clinical Study Rules, 2019 and guidelines of Central Drugs Standard Control Organization (CDSCO) etc.

SSCR will ascertain whether all cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence, and justice are taken care in the research involving human participants. SSCR aims to protect the dignity, rights and well-being of the current and potential research participants; and to ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs. SMO SOP of SSCR ensures adherence to code of research ethics, uniformity in conducting the clinical research and compliance to all applicable guidelines on clinical research. All clinical studies should be reviewed and approved by the IEC before initiation of the study, and it is mandatory to register regulatory clinical studys in the Clinical Studys Registry of India (ctri.nic.in). The investigator team should be trained in GCP/GLPor ethics in clinical research The research team should refer to study specific SOPs for further details of carrying out the specific study protocol.

SOP-1 : Preparation Of Standard Operating Procedures of SSCR

1.1. **Purpose**: To define the process for writing, reviewing, distributing and amending SOPs of SMO SSCR which ensure that the clinical research in trial site is conducted in accordance with National and International ethical guidelines.

1.2. **Scope:** Writing, verifying, reviewing, revising/amending, and issuing the site SOPs of FMRC

1.3. **Responsibilities**: The SOPs are reviewed and revised once in 2 years. In the interregnum, amendments if required are done and notified. The prepared SOPs are reviewed, approved, and issued by Director Clinical Research.

1.4. **Procedure:**

1.4.1. The author prepares a draft of SOP and sent it to the person who is authorized to review and approve for their review and approval. If there are any changes or corrections as required, the author makes the necessary corrections. The final draft is sent for final approval. Then the final documents are sent for approval and signature. This approved SMO SOP has to be followed by clinical Research team who has planned to conduct Clinical research in particular clinical study and to train the study team members, according to their expertise. When SOP has to be updated or revised, the same procedure has to be followed as done for preparation of SOP.

1.4.2. Each SOP will have following headings:

- Purpose
- Scope
- Responsibilities
- Procedure in detail
- Annexure (as applicable)

1.4.3. The header will have the title of the SOP document . The footer will have the version number,revision number, name and signature of reviewing , approving and issuing authority, date of revision and issue date.

1.4.4. Soft copy and one hard copy are available in the office of SSCR. Hard copy in PDF will be issued to the PIs and team members of the clinical research studies whenever they initiate clinical research. Soft copy in PDF will be made available in the website of SSCR for reference of all stakeholders.

1.4.5. The SOP will be reviewed once in 2 years. The procedure for preparation will be followed for revision of SOP as well. When the revised SOP is made, it becomes the current version, and the previous version will be considered "obsolete".

1.4.6. SSCR office will mark the "obsolete versions" and will keep only one copy of the "obsolete" version for reference.

1.4.7. If any changes are required in the SOP in between (other than regular revision) due to any reasons, amendments will be made. The Director of Clinical Research will assess the need for amendment and authorize the amendments and issue the soft copy in PDF within seven days of amendment approval.

SOP-2 : Training of PI and Research Team

2.1. Purpose : To describe the process for initial training and thereafter continuous training and documenting the same, and to ensure all staff members involved in clinical research at the site is properly trained according to ICH GCP, Indian GCP, ICMR and Schedule Y, SSCR SOP and other applicable regulatory guidelines.

2.2. Scope: The training will include information the investigators and clinical research personnel need to properly conduct a clinical study, including SOPs.

2.3. Responsibility:. The PI of the research team is responsible for ensuring training to all research team members. SSCR is responsible for updating the researchers on policies and SOPs of IEC.

2.4. Procedure:

2.4.1. The PI and the research team members should be trained on :

- GCP
- Guidelines from regulatory agencies
- Site SOP
- Study specific SOPs
- Policies and SOP of Institutional Ethics Committee

2.4.2. All new participating investigators and clinical research staff will be provided training to acquaint them with the principles of Good Clinical Practice and Good Laboratory practice

2.4.3. The Principal Investigator is responsible for assuring that all research team members are trained appropriately in the SMO SSCR and they have to be competent enough to conduct the study in accordance with all the regulatory guidelines.

2.4.4. Study personnel will be trained on study specific SOPs prior to working on a clinical study.

2.4.5. Training methods may include, but are not limited to classroom, computer module or webbased.

2.4.6. Training records (copies) including certificates should be retained with study records for the duration of the study.

2.4.7. After a member is trained the trainer(s) who is qualified to provide with training will have to provide them with certificate duly signed by the trainer(s)

2.4.8. The training file should be updated following each training sessions attended. Training files are to be archived with the site upon termination of employment.

SOP-3 : Communications to IEC

3.1. **Purpose** : To ensure that the PI obtains approval from IEC before initiating any research, and follows all the guidelines laid down by IEC for conduct of research

3.2**. Scope** : This SOP is applicable to all researchers, Sponsors and clinical research organizations who intend to carry out clinical research thru the SMO SSCR

3.3**. Responsibility**: It is the responsibility of the PI to apply for review and approval of protocols for conduct and reporting of clinical research thru SMO.

3.4. **Procedure:**

3.4.1. The Principal Investigator who intends to conduct a clinical research at clinical site must submit a proposal and all essential documents to the IEC before the conduct of the study to obtain an approval from the IEC .

3.4.2. The detailed protocol (with version number and date), informed consent documents, proforma / case record forms, curriculum vitae of investigators, GCP/GLP training certificates, certificates of qualification, CTRI registration documents, DCGI approval letter, insurance agreement are the minimum documents to be enclosed along with the application form.

3.4.3. PI will coordinate with ethics committee for EC meeting date and accordingly PI is responsible for submitting all the documents to the IEC in a timely manner along with EC submission letter. The PI should present the research proposal in a meeting of IEC as instructed by the IEC. He/should be give clarifications if any, and submit revisions as specified by the IEC.

3.4.4. PI may delegate responsibilities to specified study personnel for study preparation and management of communications with the IEC, the PI is the only person authorized to submit study documents to the IEC, including, a study application, renewal, amendment, adverse eventreport or termination/close-out.

3.4.5. The PI should check if the IEC approval letter has the details of the members present and if the quorum has been met, it should also contain the date time and the venue of the meeting. The PI should also check if the approval letter has the name, version number and the language used in the documents approved is the same as submitted. If the PI finds any observation or error in IEC approval it should be communicated to the IEC and request for revised approval or clarification note.

3.4.6. Any protocol amendments, deviations/violations, adverse events, serious adverse events,progress reports , study closure reports (final reports) and other updates should be submitted to the IEC in a timely manner . Protocol amendments should be implemented only after the approval from IEC.

3.4.7. Whenever the IEC asks for submission of any study-related documents as a part of monitoring of research, it is the responsibility of the PI to submit such documents and clarifications in a timely

manner. The PI should be present at the site during onsite monitoring of the study by the IEC.

SOP-4 : Informed Consent Process

4.1. **Purpose:** The Informed consent documentation process is to be obtained from all the study participants before any study related procedure has been started. The purpose of this SOP is to ensure uniform implementation of informed consent process.

4.2. **Scope :** This procedure describes the methods and practice for the review, and documentation of the informed consent process for clinical research studies and to ensure that informed consent has been obtained and properly documented.

4.3. **Responsibility** : The PI is responsible for providing a complete and valid informed consent documents , and ensuring that it meets all state, institutional and regulatory requirements. The PI is responsible for ensuring that potential study participants are informed properly and adequately regarding study procedures,

Risk / Benefits, and other deemed necessary information detailed in the informed consent; to ensure that the Informed consent used is in the language the participant understands and is comfortable ; to ensure consent from legally acceptable representative if the potential participant is not comfortable and does not understand the vernacular language; to include an impartial witness as mandated by the guidelines; documenting that study procedures were discussed with the participant and that informed ; and questions the potential participant asked and the answers given should also be documented as informed consent process.

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4.4.1. The potential participant will read and review the informed consent. He / She is given an opportunity and adequate time to ask any questions regarding the study.

4.4.2. The participant subjects should be informed the following

(a) The type study and mode of interventions.

(b) The purpose of the study and the participant's responsibilities.

(c) The treatment(s) and the probability for random assignment to each treatment.

(d) The procedures to be followed, including all invasive procedures.

(e) The reasonably foreseeable risks or inconveniences to the participant

(f) The reasonably expected benefits. When there is no intended clinical benefit to the participant,the participant should be made aware of this.

(g) The alternative procedure(s) or course(s) of treatment that may be available to the participant,and their important potential benefits and risks.

(h) The compensation and/or treatment available to the participant in the event ofstudy-related injury.

(i) Compensation for the anticipated expenses, if any, to the participant for participating in thestudy.

(j) The approximate number of participants involved in the study .

(k) That the participant's participation in the study is voluntary and that the participant may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.

(l) That the monitor(s), the auditor(s), the IEC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical study procedures and/or data, without violating the confidentiality of the participant, to the extent

permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the subject's legally acceptable representative is authorizing such access.

(m) That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, the participant’s identity will remain confidential.

(n) That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the study.

(0) The person(s) to contact for further information regarding the study and the rights of study participants, and whom to contact in the event of study-related injury.

(p) The foreseeable circumstances and/or reasons under which the participant's participation in the study may be terminated.

(q) The expected duration of the participant's participation in the study.

4.4.4. If the participant agrees to participate, the participant will sign and date the consent form on the appropriate place

. 4.4.5. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible, and the participant's Legally Acceptable Representative (LAR) is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented approval/ favorable opinion by the IEC, to protect the rights, safety and well-being of the participant and to ensure compliance with applicable regulatory requirements.

4.4.6. The participant or the participant's LAR should be informed about the study as soon as possible and consent to continue and other consent as appropriate should be requested. Any queries regarding the study or related asked by the participant should be answered by the Principal Investigator or the designate to the complete satisfaction of the participant

SOP-5: Procedure for Screening and Enrollment of Research Participants

5.1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the procedures used by the Principal Investigator and his / her team to identify eligible subjects for a study.

5.2. **Scope**: All clinical research using human subjects conducted at FMRC should maintain a subject screening and enrollment log and thus are responsible for screening and enrolling appropriate patients.

5.3. **Responsibility**: The Principal Investigator is the ultimate responsible person for identifying the eligible subject and enrolling them in the study. PI can even delegate the responsibility medical staff of the study team provides PI supervises.

5.4**. Procedure:**

5.4.1. The potential subjects for participation in the research will be based on the research protocol.

5.4.2. **Screening**:

- The patients who may fit into the inclusion and exclusion criteria visiting the site can also be informed about the study.
- Before screening procedure is started all the medical records available with the patient should be collected and a detailed medical history taken. If from any of the inclusion and exclusion criteria the patient does not fit in the study then they need not be screened but if the Principal Investigator feels we can try with the screening process, then the patient can be screened according to the screening process after obtaining a voluntary informed consent, a photocopy of the same can be collected.
- All patients who voluntarily consent to participate should sign and date consent form. A photocopy of the signed dated informed consent should be given to the subject. All study related procedures shall be performed only after the patient provides written informed consent.
- Principal Investigator should make sure that eligible patient is not participant of any other study or should not have been participant of a study if protocol necessitates
- On randomization the Principal Investigator and the team should properly and clearly instruct the subject, the importance of drug compliance, the visit(s) and the investigation.
- If there are any specific instructions that has to be given to the subject, then all the instructions have to be provided to the subject.
- More than one contact details of the subject have to be obtained from the subject.
- a) Once the patient is found to be fit according to the inclusion and exclusion criteria, the subject can be randomized according to the protocol. The randomized subject will be provided with subject identification card.
- The Principal Investigator should inform the subject that in case he / she experience any untoward event (AE/SAE) he / she should contact the PI or the site team immediately.
- If a subject wishes to withdraw consent at any point of the study, the PI should make reasonable efforts to keep the patient informed the importance

of continuing in the study but there should not be any coercion for the subject to continue in the study.

- However, the decision to participate or continue in the study shall solely lie with the subject.

SOP-6 : Handling Investigational Product (IP)

6.1. **Purpose :** To describe requirements for control and record keeping of the inventory for Investigational Product.

6.2. **Scope** : SOP covers control and record keeping of all the IP obtained for use in human subjects' research. "Test article" includes the Investigational Product(s) which may be a drug or device, placebo(s) and/or comparator(s) used in the clinical study.

6.3. **Responsibility:** This SOP applies to the Principal Investigator and to delegated staff who is assigned for dispensing, control or inventory management of any IP

6.4**. Procedure :**

6.4.1. An Investigator shall permit an IP to be administered or used only by subjects after obtaining consent for participation in the study and should be done only under the investigator's personal supervision. The PI may delegate Co investigator or a Sub- Investigator, who is responsible to the Investigator, to administer or dispense the test article. Though the designated person dispenses the IP, the accountability is with the PI

6.4.2. The received IP should be checked for any damage, quantity and maintenance of temperature. On receipt of the IP the concerned should be informed accordingly.

6.4.3 Investigator or the designated should identify the IP and it should be given to the correct participant in the correct dosage as specified. The participant should be explained in detail the appropriate use of the IP.

6.4.4. If the participant develops any reaction, he/ she should be instructed to inform the PI or the authorized person immediately

6.4.5. The IP should be stored in appropriate temperature, and should be recorded and documented. The IP storage area should be with limited access and should be recorded.

6.4.6. Accountability log should be maintained, the details should include the dates, batch number and if any code numbers, the total quantity received, quantity dispensed and returned by the participant and if there were any over dosage or any missed IP and the quantity returned to the sponsor or their representative or destroyed at the site

6.4.7. When the study is completed or discontinued the PI may return the remaining supply of IP to the sponsor or destroy the same as per regulations and with necessary precaution. This can be done only after the sponsor informs the PI.

6.4.8. IP should not be used by the PI for any commercial use or in any other study.

SOP-7 : Procedure for Source Documentation

7.1. **Purpose** : To describe the importance of source data and maintenance of Source documents during the conduct of a Clinical study

7.2. **Scope:** This SOP will cover all the documents which will form the Source Documents that will be used in clinical study and how the Principal Investigator and the team are responsible for maintaining the source documents.

7.3. **Responsibility**: The study team members like Principal Investigator, Co Investigator, Sub Investigator, Clinical Research Coordinator and other staff involved and who are authorized for accurate data collection, accurate reporting, interpretation and verification of the data collected and to maintain all the documents as specified in ICH GCP/GLP and other regulatory guidelines.

7.4**. Procedure:**

7.4.1. The Principal Investigator or the designee's responsibility is to take complete detail medical history (As required in the protocol) orally and by the reports that the patient has.Thus collected data has to be entered in the hospital notes.

7.4.2. The original or the certified documents of the study participants pertaining to their illness, medical history or laboratory reports are considered as source document.

7.4.3. After the entries are made in the source documents if there are any corrections, appropriate corrective techniques has to be used. Original entry must be legible; the original entries should not be erased; whitener or any corrective fluids) should not be used; there should not be any overwriting

7.4.4. The corrections in the entries made should be: Only a line across the entries made and sign anddate for the corrections made. If there are new entries to be made then the reasons for changes made have to be documented and initialed and date the corrections

7.4.5 The laboratory reports have to be reviewed by the Principal Investigator and initialed and the date has to be entered.

7.4.6. The photocopies will include but not limited to old hospital / clinic reports (both OPD and inpatient hospitalization) , ECG, X-ray and any other imaging report Lab reports , medical charts, old prescriptions, any other medical referrals and consultations.

7.4.7. All source documents have to be archived according to the sponsor or as per the regulatory guidelines.

SOP-8: Procedure for Reporting Adverse events (AE) and Serious Adverse Events (SAE)

8.1. **Purpose** : To define the way in which the safety reporting like Adverse Events and Serious Adverse Events are reported.

8.2. **Scope** : For all the clinical research work done under SMO SSCR

8.3. **Responsibility** : Once the study is started and the participant has been enrolled into the study all the study team members including the Principal Investigator, Co – Investigator, Sub – Investigator,Clinical Research Coordinator and Nurse and other study related staffs are responsible for continued surveillance of AE, and SAE. In case if a situation arises the PI or the study team will report any such events promptly to the according to the prevailing guidelines.

8.4. **Procedure:**

8.4.1. **Definitions:**

1) **Adverse Event (AE)**: An unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events may be mild, moderate, or severe, and may be caused by something other than the drug or therapy being given..

2) **Adverse Drug Reaction (ADR):** An injury caused by taking medication, may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs. .

3) **Unexpected Adverse Drug Reaction:** An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. Investigator's Brochure for an unapproved investigational medicinal product).

4) **Serious Adverse Eve**nt: An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanentimpairment or damage.

8.4.2. The Principal Investigator or the designee will instruct the participant to inform the site immediately if they are taking any tablets or meeting a doctor for any kind of illness. They would also be advised that they should have the prescription and laboratory reports (if any) to keep it safe and show to the study team member during their next visit to the site. The study team member photocopies the same and should follow with the participant until the resolution of the AE.

8.4.3. It will be the responsibility of the Principal Investigator to provide with adequate medical facility for the participant. The medical care thus provided by the sponsor should be entered in the source.

8.4.4. If there are any abnormal lab values the PI should review whether they are clinically significant or very high or very low, enabling the participant to get admitted, then they are termed as SAE and the routine procedure is followed.

8.4.5. The AE should be assessed for causal relationship with the study medication and the seriousness of the AE should be assessed.

8.4.6. **Serious Adverse Event Reporting:** Any Serious Adverse Event (SAE) has to be reported according to the prevailing guidelines to the Sponsor, IEC and regulatory authorities .Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE; Due analysis will also be submitted by the sponsor within 14 days.

8.4.7. Until the event is resolved the SAE should be followed up until resolution and the follow up report should be sent to the concerned.

8.4.8. All the information regarding the SAE should be documented in the source documents. The details in the SAE form should be captured only from the source. The fully completed SAE form should be signed and dated by the concerned as mentioned in the study specific site delegation log, and the SAE form should be shared with the person designate of the sponsor.

SOP 9: SOP for Archival of study documents

9.1: **Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe the standard procedures to be followed when archiving essential paper/electronic documents related to clinical research/trial All trial data must be kept so that the data can be accessed after the trial is completed

9.2: Scope

For all the clinical research work done under SMO SSCR

9.3. Responsibility:

Archivist or designated personnel are responsible to follow this SOP during archival retrieval and re-archival of documents / data. Relevant department personnel have to follow this SOP while submitting documents for archival / re-archival and requesting for retrieval of documents / data.

9.4. Definition

Archival: The procedure of preserving documents in any media for longer storage, in a safe environment with controlled access.

Retrieval: The procedure of getting the documents from the archives for reference,

regulatory requirements etc.

Re-archival: The procedure of re-archiving the documents after the purpose of retrieval is completed.

Clinical Trial: Any investigation in human subjects, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other Pharmacodynamic effects of one or more medicinal product or to identify any adverse reactions to one or more such products and to study absorption,

distribution metabolism and excretion in one of more such products with the object of ascertaining the safety or efficacy of those products.

Essential Documents: Essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. This includes the **Trial Master File, source documents and Case Report Forms (CRFs).**

Trial Master File: The Trial Master File is a file that consists of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated. Those documents shall show whether the investigator and the sponsor have complied with the principles of Good Clinical Practice and with the applicable regulatory requirements

Source Documents: Source documents are original documents, data, and records (e.g.,hospital records, clinical and office charts, laboratory notes, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)

Case Report Forms (CRFs): This is a printed or electronic document designed to record all of the protocol required information on each trial subject.

9.5 Archival Room Maintenance and Access control

Access to archives is restricted to Archivist and Administration. Entry of other individuals Third Party employees and external personnel such as Auditors / Clients) into the archival facility shall be escorted by the archivist during visit. Entry and exit details shall be captured in the logbook as per Annexure 01 – Entry and Exit of Archives. Archival room is provided with the CCTV Camera, fire extinguisher, Heat and smoke detector. The temperature of 23(+/-) 4oC and

humidity 30-70% RH shall be maintained in archival room.Pest control activity

Protocol No.:	
Investigator	Centre No.

shall be performed quarterly or as whenever required

The archivist shall perform quality check of the archives once in 06 months by visual audit for any signs of deterioration like Paper Mites, dust, rodents / insects excreta and moulds. For any deterioration noticed, ensure immediate remedial actions are taken

9.6 Archival period: All essential documents relating to clinical study including monitoring documents, projectsfiles and audit documents shall be archived in accordance with the requirements of the applicable regulations / guidelines

9.7 Disposition of archived data/documents: Upon completion of the contracted archival period, the sponsor shall be informed/intimated in writing. If the archival period is not extended by the sponsor, then the study documents shall be returned to the sponsor and a list of documentation provided to the sponsor shall be created. A sponsor acknowledgment copy of this shall be retained.

SCREENING AND ENROLLMENT LOG

Screening No.	Screening Date (DD/MM/YY)	Subject Initial	Enrolled Yes/No	Patient ID allocated (if enrolled)	Screening Failure Reason	Signature

Entry and Exist register of Archives

S.No	Name of the Person	Department/ Sponsor/ Regulators	Purpose	Time in	Time out	Sign and	Date

Retrieval Data Form

S.No	Protocol No.	Request for with date	Retrieved by with signature	signature Returned Date and signature	Authorized by

Destruction Form

S.No	File/Document No	Box/Shelf No	No.of Boxes	Date of destruction	Verified by

References

- New Drugs and Clinical Study Rules, 2019 : CDSCO
- ICMR , National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
- CFR 312.55-Informing Investigators
- CFR 312.57- Record Keeping and Record Retention
- 3. 21 CFR 312.58- Inspection of Sponsor records and Reports
- 4. 21 CFR 312.62- Investigator Record Keeping and Record retention
- 5. 21 CFR 312.64- Investigator Reports
- 6. Appendix V-CDSCO guideline: Essential Documents
- 7. ICH Guidelines for GCP (E6) Section 4.4- communication with IRB/IEC
- 8. ICH Guidelines for GCP (E6) Section 4.9- Records and reports
- 9. ICH Guidelines for GCP (E6) Section 5.22- Clinical Tail/Study Reports