BIRAC CTN Clinical Research Secretariat

Standard Operating Procedure

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Standard Operating Procedure

Clinical Research Secretariat (CRS)

Title: Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Clinical Research Secretariat (CRS of <name of institute>)

SOP Code: SOP 01/V1.1 **Date: 19/Jan/2022** **Pages: 4 to 14**

1.1 Purpose

This SOP describes the process for writing, reviewing, distributing, and amending SOPs within the CRS of the institute and also to provide a tool for training new personnel in the procedures by which specific activities will be performed at institute.

This SOP will provide clear, unambiguous instruction to conduct activities of the CRS in accordance with the ICMR guidelines 2017, New Drugs and Clinical Trials Rules, 2019, (NDCT Rules 2019), ICH (International Council on Harmonization) Good Clinical Practice (GCP) E6/R2, Indian GCP guidelines 2002, and all other regulatory guidelines as issued from time to time and Gazette notifications and its amendments as issued from time to time.

1.2 Scope

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the CRS of the Institute.

1.3 Procedure

Institutional Research Head will determine the activities which require SOPs and will appoint SOP team to formulate the SOPs. SOP team will prepare the draft of the SOPs with description of the procedure (i.e., a detailed description of all tasks to be conducted under the SOP, including when they are to be accomplished, where, and by whom). The draft SOPs will be reviewed by SOP review team. SOP team will be responsible to amend the SOPs as and when required.

Each step in the procedure should be numbered. All new or unusual terms should be defined. If an abbreviation is associated with a term, it should be placed in parentheses following the word.

SOPs will be prepared by the SOP drafting team of the institute. The Institutional Research Head will review the SOPs. The SOPs will then be signed and dated by the preparer, reviewer (Head of Institutional CRS) and approved by the Director of the institute as these are for conduct of research studies at institute.
SOP team members will be assigned by the Institutional Research Head. They may include experienced administrative staff/CRC/Project Manager.
The team will-

- Draft the SOP
- Review of SOP
- Assess the request(s) for SOP revision
- Propose a new, or modification in existing SOPs as needed
- Select the format and coding system for the SOPs
- Submit the draft for approval
- Review and sign and date SOPs

CRS Core team

- Co-ordinates activities of writing, reviewing, distributing, and amending SOPs.
- Maintains on file all current SOPs and the list of SOPs.
- Maintain a file of all SOP amendment requests.

- Maintains an up-to-date distribution list of each SOP circulated.

- Maintain a record of the investigators to whom SOPs are distributed
- Ensures that all members involved in conducting research at institute have access to the SOPs
- Maintain a file of all previous SOPs of the CRS
- Assist in the formulation of SOP procedure

1.3.1. Identify the need for new or amendment to the SOP

Any member of the CRS, SOP review team, Investigator or other research team member, can make a request for revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP, can put forth his / her request by using the Request Form for Formulation of new SOP/ Revision of an SOP Form (AX5-V2/SOP01/V2). This Formulation of new SOP/ Revision of an SOP Form (AX5-V2/SOP01/V2) are submitted to the Institutional Research Head will inform SOP review team Committee.

Upon request and if agreed upon the Institutional Research Head will appoint an appropriate SOP team comprising of core team for SOP revision. The Institutional Research Head may also appoint one or two experienced Clinical Trial Coordinator (CRC), if necessary. This designated team will proceed with the task of revision / formulation process of the SOP.
If the Institutional Research Head and SOP review team do not agree to the request, no further action will be taken.

1.3.2 List of relevant SOPs

- Write down step by step all the procedures for conduct of research
- Organize, devise and name each process
- Make a list of SOPs with coding format (e.g. AX1-V2/SOP01/V2)

1.3.3 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood

A unique code number with the format SOP xx / Vy will be assigned to each SOP. xx is a two-digit number assigned to a specific SOP. “V” refers to version of the SOP and “y” is a number identifying the version e.g. SOP01/V2 is SOP number 01 with V=version no.02

Each Annexure (AX) is unique code with format AXn–Vp/SOP xx/Vy. e.g. AX1–V2/SOP01/V2 indicates AX is Annexure, 1 is Annexure no., V2 is version 2, belonging to the SOP 01/V2

Each Appendix will be given unique code with the format APPn/Vy e.g. APP1/V2 indicates APP is Appendix, 1 is Appendix no 1 and V2 is Version no.2

Each SOP will be prepared according to the template for Standard Operating Procedures (AX2-V2/SOP01/V2). Each page of the SOP will bear a header with the effective date which is the date of acceptance of the SOPs by the director, Institute.

1.3.4 Write, Review and Approve SOP

Preparer team-persons assigned by the Institutional Research Head
Reviewer team-Institutional Research Head
Approver-Institute Director
All the three will sign and date their activity.

1.3.5 Review by Consultation

- The draft SOP may also be reviewed by 3-4 additional members of SOP review team (if required)
- The SOP will be finally reviewed and signed off by Institutional Research Head.

1.3.6 Final Approval of new/revised SOP

- The reviewed SOP will then be submitted to the institute head for approval and sign off.
- The date of approval and sign off by the Director will be considered as the effective date for implementing the SOP.

1.3.7 Implementation, distribution and filing of SOPs

- Approved SOPs will be implemented from the effective date.
- The Institutional Research Head will ensure that the SOPs are shared with all the Investigators of the institute so that they can be implemented from the effective date.
- The SOPs will be distributed as per Institutional distribution list.(AX4 –V2/SOP 01/V2)
- When revised version is distributed, the old version will no longer be effective. A copy of the old version will be archived in a master file.
- One complete original set of current SOPs will be archived in the SOP master file, by the CRS and maintained in the CRS Office.
- Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by the Institutional Research Head or authorized individual. A distribution log should be maintained (AX6 –V2/SOP 01/V2)

1.3.8 Review and request for revision of an existing SOP

- Any member of the CRS core team or researchers in the institute who observes that current SOPs have some deficiency or have any suggestions to improve a procedure should make a written request, using a form (AX5-V2/SOP 01/V2)
- If CRS and SOP review team agrees with the request, the Institutional Research Head will appoint an appropriate team for the revision process..
- The same procedure will be followed for drafting, reviewing and approval of the SOP.
- The Institutional Research Head will the review of the SOP at least once every 3 years, from the effective date of the SOPs.

Training on revised SOPs:

1. The Institutional Research Head will share the SOPs as soft copies with each DMG Convener/departmental heads and DMG/departmental coordinator (if applicable).
2. It will be the responsibility of the Convener/ departmental head to ensure that all the research staff are trained on the SOP and relevant training records are maintained.

1.3.9 Manage and archive old SOPs

Old SOPs should be retained and clearly marked “superseded” and archived in a file by the secretariat. The process of evolution of previous SOPs of the IEC will be documented in secretariat. The process of evolution of previous SOPs of the CRS will be Documented in a defined format (AX3 –V2/SOP01/V2).

AX1-V1/SOP 01/V1.1

List of SOPs of Clinical Research Secretariat

Sr. No	SOP TITLE	SOP CODE	Page Nos.

AX2-V1/SOP 01/V1.1

Template for Standard Operating Procedures

Clinical Research Secretariat	
Title: Title which is self explanatory and easily understood	
SOP No: SOPxx/Vy	Page: a of b
SOP Code: SOP xx/Vy **Effective Date:** DD/MM/YYY **Authors:** xxxxxxxxxx **Reviewed by:** xxxxxxxx **Approved by:** xxxxxxx	

AX3-V1/SOP 01/V1.1

Details of superseded SOP

Name of the Team	Version	Type (draft/final)	Effective Date (If final) (dd-mm-yy)	Describe the main change

AX4-V1/SOP 01/V1.1

Log of the CRS members, SOP review members and PIs receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

No.	Name of trainee	Designation	Recieval of training (Yes/no)	Assessment satisfactorily passed (Yes/No)	Signature	Date

AX5-V1/SOP 01/V1.1

Request for Formulation of new SOP/ Revision of SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP No.		
Title:		
Details of problems or deficiency in the existing SOP		
Need to formulate an entirely new SOP (i.e. SOP not existing previously)		
Identified by:		Date (DD/MM/YYYY):
Discussed with CRS core team on:		
SOP revision required:	☐ Yes	☐ No
New SOP to be formulated:	☐ Yes	☐ No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP revised:		
Date SOP approved:		
Date SOP becomes effective:		

AX6-V1/SOP 01/V1.1

Log of SOP recipients

No.	Name of the Recipients	Designation	SOP code number	No. of copies	Date
1	**Xxxxx**	**xxxxx**			
2	**Xxxxx**	**xxxxx**			
3	**Xxxxx**	**xxxxx**			
4	**Xxxxx**	**xxxxx**			
5	**Xxxxx**	**xxxxx**			
6	**Xxxxx**	**xxxxx**			

Standard Operating Procedure

Clinical Research Secretariat (CRS)

Title: Assessing Protocol feasibility; for Investigator initiated & Sponsor/Pharma Studies

SOP Code: SOP 02/V1.1 Date: 19/Jan/2022 Pages: 15 to 26

2.1 Purpose

To describe the procedures for assessing the feasibility of conducting a study at the institute in compliance with standard protocol, for Investigator initiated studies & sponsor/Pharma studies. The institute is committed to maintain the highest scientific, clinical and ethical standards while conducting research at the institute. Further, institute is committed to comply with all applicable regulations and guidelines in this regard. In view of the same, before agreeing to participate in a clinical research study, the Principal Investigator (PI), department consultants and Institution must agree to the scientific, clinical, and ethical merits of the study; the financial impact to the hospital; compliance with regulations; and the operational feasibility of conducting the study at the institute. This standard operating procedure (SOP) describes the steps for assessing the feasibility of conducting a study at institute.

Additionally, Institution and PI considers the potential benefits of proposed studies to cancer control in the institute and development of the state's research portfolio.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within the institute research network.

2.2 Scope

This SOP applies to the activities involved in assessing protocol feasibility for all research studies conducted at the institute involving human participants.
This SOP applies to the assessment of protocols and funding for Investigator initiated & sponsor/pharma studies.

2.3 Procedure

2.3.1 Protocol Assessment

The principal Investigator & his team members will assess whether the proposed protocol is feasible to conduct with the existing staff and facilities. PI can use protocol checklist to ensure if it is feasible to conduct the study, as per the available protocol, at the institute (AX1-V1.1/SOP 02/V1.1).
In case of Sponsor study, a structured feasibility questionnaire may be provided to the site by the Sponsor. In such a case the Protocol checklist will not be applicable.

The PI may discuss all the protocol (Investigator initiated research or pharmaceutical sponsor trial) with his respective research team meeting and seek their inputs for the conduct of the study.

The Investigator (with the help of his research team members, and any other appropriate site personnel) may review the protocol to ensure the following:

2.3.1.1 Clinical/Scientific/Ethical Feasibility

- Clinical importance to institute patients.
- Scientific merit.
- Benefits and risks associated with the protocol.
- Consistency with the priorities of the hospital and the clinical department.

2.3.1.1 Operational Feasibility

- Availability of personnel and other resources required to conduct the study.
- Availability of patient pool meeting the inclusion / exclusion requirements of the study.
- The level of interest/time expected from the physicians needed to recruit patients into the study.
- The operational complexity of the protocol.
- Whether there are any conflicting studies in progress where competitive enrollment is a possibility.

2.3.1.2 Regulatory/IEC Feasibility

- The PI reviews the protocol to determine whether there is any additional requirements to be considered when submitting the project to the IEC. Additional requirements can be in the form of specific local IEC required documents (eg – MoU, CTA, etc.), specific local format of some study documents to be met (eg – ICD, protocol, etc.) as part of the review the PI can consult with IEC administrator or the Member Secretary. We need to be more specific here.
- PI to evaluate whether HMSC approval is applicable for the study.

- The PI should check the following points before submitting the protocol to the IEC for approval):
  - Research studies have the resources/procedures in place which would be necessary to protect participants:
  - Adequate time for the researchers to conduct and complete the research.
  - Adequate number of qualified staff for the conduct of the study
  - Adequate facilities like required patient pool, trained and experienced team members and intervention facilities.
  - Access to a population that will allow recruitment of the necessary number of participants.
  - Availability of medical or psychosocial resources that participants might need as a consequence of the research.

2.3.1.4. Financial/ Legal Feasibility

- A detailed review of the costs, including staff time needed to complete protocol activities and patient care visits are determined by the PI.
- The PI and CRC may prepare the budget worksheet with the required expenses
- In case of a sponsored study a tripartite agreement (CTA/CSA) should be in place
- In case if IIR with funding, an appropriate MoU should be available between the funding agency and the Investigator. This funding may be iun the form of the research grant/study drugs/equipment etc.
- If required the PI may get the MoU/tripartite CTA reviewed by the Institutional legal department.

2.4 Applicable departments of the site/departments of the institute

This SOP applies to all the researchers, research departments and research team.

2.5 Staff responsible for Implementation

This SOP applies to all the researchers, research departments and research team.

AX1-V1/SOP 02/V1.1

PROTOCOL FEASIBILITY CHECKLIST

Factors to consider:

1. Population	
Do you have access to the right patient population?	
Will you need to recruit participants from external sources? If so, will sponsor provide funding?	
Is the proposed enrollment goal realistic?	
Is the proposed enrollment period realistic?	
Will enrollment compete with other studies seeking the same participants?	
Are inclusion/exclusion criteria overly restrictive? (Consider the likely screen failure ratio and the number of screen failures)	
Do you expect a significant number of adverse events? (How ill is this population?)	
2. Protocol	
Is the protocol well designed?	
Is the protocol ethical? Will the IRB have problems with it?	
Is the study question important?	
Will the participants risk/benefit from participating in the study?	
Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written? (In case of sponsored study)	
Can other services (e.g., lab, radiology) meet the protocol requirements?	
Is necessary equipment available?	
Are participant's compliance problems likely? If so, will it be necessary to monitor participants' compliance with time-consuming phone calls or postcards?	
Are case report forms complex?	
Are drug or device storage/accountability requirements complicated?	
Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)	
3. Procedures	
Are procedures frequent?	
Are procedures difficult, e.g., elderly participants asked to swallow pills?	
Are procedures painful?	
Is the dosing schedule complex?	
4. Staff	
Are qualified staffs available	
If needed, is training available?	
Does the PI have adequate time to devote to the protocol?	
Are additional specialists needed?	
Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study-staff will participants encounter in a given visit?	
5. Budgets	

Does preliminary budget appear adequate? (Sponsors or investigator generated)	
If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities, e.g., IEC submission, meetings, chart reviews?	
Will sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?	
Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?	
Any other protocol required equipments or procedures etc.	
6. Other	
Is adequate space available for study conduct and storage?	
Will electronic or remote data retrieval systems be used? If so, will sponsor provide training?	
Does the sponsor/PI expect this study to be audited by the regulatory bodies?	

Feasibility questionnaire template
AX2-V1/SOP 02/V1.1

Study Title:

Sponsor Principal Investigator:

Coordinating Centre:

Site Feasibility Questionnaire		
Sr. No.	**Feasibility criteria**	**Please fill in the details**
1	Name of site	
2	Contact details of the site	Address: Telephone: Fax: Email:
3	Type of site (Please tick)	○ Government hospital ○ Private hospital ○ Charitable Trust Hospital ○ Primary care physician ○ Other
4	Does the site/PI have standard operating procedures (SOPs)?	○ Yes ○ No
Comments (if any):		
Site Resources		
Research staff		
5	Details of the Principal Investigator	Name: Designation:
6	Credentials	○ MD ○ MS ○ MCh ○ PhD ○ DM ○ Other
7	Contact details of the Principal Investigator-	Address: Telephone: Fax: Email:

8	Contact details of the coordinating person (Investigator/CRC)?	Telephone: Email:
9	Does the PI have time to conduct this study?	○ Yes ○ No
10	Does the PI have interest to conduct academic research?	○ Yes ○ No
11	Professional Experience of the PI (in years)	
12	Clinical Research Experience of the PI (in years) as a PI/CoI/research fellow/thesis?	
13	Does the PI have experience in global clinical trials?	○ Yes If Yes, please specify the phase of the trial: ○ Phase I ○ Phase II ○ Phase III ○ Investigator Initiate Study ○ Post Marketing Surveillance ○ No
14	How many clinical studies are currently ongoing under the PI's supervision?	
15	Research publications of the PI	○ Number of International publications- ○ Number of National publication-
16	Is the PI GCP Trained? (If Yes, Mention the date of training, Name of Training/Certification Body)	○ Yes ○ No
17	Does site have dedicated staff to conduct Research?	○ Yes ○ No
18	Number of research staff and supportive staff	Number of Co-Investigators- Number of Study Coordinators- Any other (Study Nurse/Pharmacist etc.)- Please specify the number
19	Does the staff have experience with e-CRF?	○ Yes ○ No
20	Is the site staff (other than the PI) GCP trained?	○ Yes ○ No
Comments (if any):		

Laboratory details		
21	Is Local laboratory facility available?	○ Yes ○ If No, please specify the name of the laboratory whose services would be used.
22	Is the laboratory accredited?	○ NABL ○ CAP
23	Does the site have facility for Radiology Investigations?	○ Yes ○ No
24	Please tick facilities available	○ X-ray ○ CT scan ○ MRI ○ USG ○ Bone Scan ○ PET ○ ECG ○ 2D ECHO ○ Other (Please specify any additional investigational facilities in the comments section)
Comments (if any):		
Space and Facilities		
25	Does the site have dedicated space for research activities?	○ Yes ○ No
26	Does the site have space for storage of study related materials (lab kits)?	○ Yes ○ No
27	Does the site have separate room for Monitoring?	○ Yes ○ No
28	Does the site have infrastructure for storage of blood and tissue sample?	○ Yes ○ No
29	Does the site have space for Archival of data after completion of the trial? If yes provide the details and procedures? If no specify the location where	○ Yes ○ No

	documents will be stored?	
30	Does the site have dedicated cupboard for study document storage?	○ Yes ○ No
31	Does the site have dedicated Refrigerator or cold storage facility for IP storage facility with temperature control?	○ Yes ○ No ○ NA
32	Does the site have sample processing facility? If Yes, Give details	○ Yes ○ No ○ NA
33	Does the site have a separate room for AV recording?	○ Yes ○ No
34	Does the site have Internet facility	○ Yes ○ No
35	Does the site have STD/ISD/Fax call facility?	○ Yes ○ No
	Comments (if any)	
Patient Recruitment Strategy		
36	What is the number of patients (per month) seen in the Hospital of particular indication involved in the trial?	
37	How does site recruit patient?	○ Database ○ Referrals ○ Internet ○ Newsletters ○ Advertisements ○ Other
38	Besides English which other Vernacular ICDs/Patient related documents would be required?	
Protocol Specific (To be pre-filled by CRA/CTA before sending the FQ to site)		
39	Total sample size (all sites)	

40	Inclusion criteria	
41	Exclusion Criteria	
42	How many patients would fit the eligibility criteria of the trial? How many patients would the site /PI be able to recruit?	Patients eligible for trial per month: …… Patients to be recruited per month: …….
43	Have the PI conducted any clinical trial with similar indication?	o Yes o No If yes, please state the number-
44	Are there any ongoing competing clinical trials for a similar indication?	o Yes o No If yes, please specify details (Sample Size, No. of patients enrolled till date, CTRI No etc.)
Comments (if any):		
Ethics Committee		
45	Does the Institute have any Institutional Ethics Committee?	o Yes o No
46	Kindly provide the contact details of EC administrator/ member secretory	IEC Contact person Address Telephone: Fax: Email:
47	a) Is the IEC registered with DCGI? b) Is the IEC registered with DHR (Department of health research, ICMR)? c) IS NABH assessment of IEC performed?	o Yes o No If yes, please mention the registration number and the validity period- o Yes o No If yes, please mention the registration number and the validity period- o Yes o No

		If yes, please mention the accreditation number and the validity period-
48	Is the EC constituted as per the New drugs and CT rules/ ICMR?	○ Yes ○ No
49	Does IEC have a written SOP?	○ Yes ○ No
50	What is the frequency of IEC meetings? Please provide the dates of the previous and upcoming IEC meeting	
51	How many days prior to the meeting should the study documents be submitted?	
52	Is checklist for submission of documents for IEC review available	○ Yes ○ No
53	How many copies of documents are required for submission?	
54	How many days after the meetings will the approval letter be issued?	
55	EC fees (if any) for academic research studies	Initial review: …… Amendments documents Review: …… Any other review fee: ……
Comments (if any):		
Finance		
56	Does the site have any research specific account where study related payments can be made? I f Yes, please mention the mode of payment (cheque/fund transfer), PAN & GST details	
57	Admission Charges-	
58	Bed Charges-	
59	ICU charges-	
60	Please specify the cost of Blood Investigations (Enclose the current schedule of charges/ Rate card)	Haematology: Biochemistry: Others:
61	Please specify the cost of radiology and other investigations (Enclose the current schedule of charges/ Rate card)	○ X-ray ○ CT scan ○ MRI

		○ USG ○ Bone Scan ○ PET ○ ECG ○ 2D ECHO
Comments (if any):		

Filled by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Site Initiation

SOP Code: SOP 03/V1.1 **Date: 19/Jan/2022** **Pages: 27 to 30**

3.1 Purpose

To describe the process that ensures that the site is organized and prepared for the conduct of the research study at the Institute. This standard operating procedure (SOP) also describes the processes to be followed at site initiation at the Institute.

3.2 Scope

This SOP will apply to all research studies [whether IIR (Investigator Initiated Research) or pharma sponsored] initiated at the institute.

3.3 Procedure

The site initiation process is designed to ensure that;

- Site has all essential documents in place for the site to conduct the study in compliance with the approved protocol and applicable guidelines and regulations. DCGI and Ethics Committee approval for sponsored studies and IEC approval for Investigator initiated studies.
- CTRI registration is in place
- PI to ensure that he and his study team is aware of all the Institutional SOPs for study conduct.
- Site meets all the study related requirements for recruiting patients.

3.3.1 For Investigator Initiated Studies:

A. Related to Trial Master File:

Ensuring the availability of the TMF containing the following:

- IEC approval and all IEC communications since initial submission
- CTRI registration
- IEC approved Final Protocol
- IEC approved CRF
- IEC approved ICD in English, Hindi and other local languages as applicable
- Package insert of standard of care marketed drugs used as comparator (if applicable)
- Investigator Undertaking
- Signature and duty delegation log
- CV, GCP and MRCs of all Investigators /Sub-Investigators
- CV, GCP of other research team members
- All applicable logs including screening/ patient ID/ drug accountability log etc.
- Any signed executed MoU if applicable

B. Preparation for Site Initiation Visit

In case of IIR, the Sponsor Investigator confirms with his team for availability regarding a detailed training on the Protocol and applicable study requirements. The study team may include Co-I/ CRCs/ Research Nurse/Radiologist/Pathologist as applicable.

C. Related to Protocol training:

- The Sponsor Investigator to train the entire team on the following and document the training in a training log:
- Protocol
- Advise the relevant staff regarding drug inventory
- Training on IC process
- Training on SAE reporting timelines

3.3.2 For Sponsored Studies:

A. Related to ISF:

Ensuring the availability of the ISF containing the following:

- DCGI approval
- IEC approval and all IEC communications since initial submission
- CTRI registration
- IEC approved Final Protocol
- IEC approved CRF
- IEC approved ICD in English, Hindi and other local languages as applicable
- Investigator Brochure
- Package insert of standard of care marketed drugs used as comparator(if applicable)
- Investigator Undertaking
- Signature and duty delegation log
- CV, GCP and MRCs of all Investigators /Sub-Investigators
- CV, GCP of other research team members

- All applicable logs including screening/ patient ID/ drug accountability log etc.
- Any signed executed MoU /CTA
- Normal Laboratory Reference range
- Financial Enclosure
- Any other manuals as applicable like laboratory/ CRF completion manual etc.

B. Preparation for Site Initiation Visit

For sponsored studies, the CRCs should confirm the availability of the PI/applicable team members for a site initiation visit (SIV) by the Sponsor. CRC to ensure that a detailed agenda is received from the Sponsor.

PI/CRC should check for the availability of all the resources like adequate space for IP and any other study related material, availability of the final signed CTA etc.

C. Related to Protocol training:

The CRA/Sponsor representative will train the PI and the entire team (all those specified in the duty delegation log) on the following:

- Detailed Protocol
- IC process including AV recording
- IP accountability
- Safety Reporting
- Completion of paper/electronic CRF and its timelines
- Source documentation
- Process of patient recruitment and timelines
- Completion of all logs
- On all the laboratory/specimen collection/ lab kits manual.
- Demonstration of IWRS/IVRS (if applicable)
- Facility tour may be undertaken by the Sponsor representative including visit to the Pharmacy to review the storage of the IP at the site.
- To document the training in training log
- To discuss any open action items if any with the Investigator and team
- Send the SIV record to the PI for filing in the ISF.

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Study Conduct

SOP Code: SOP 04/V1.1 **Date: 19/Jan/2022** **Pages: 31 to 33**

4.1 Study conduct

Once the site is activated and starts recruiting participants, the Investigator and CRC will ensure the following:

- All study activities are accomplished according to the approved protocol, SOP, guidelines and applicable regulations.
- Participants sign the IEC approved version of the consent form before any study-related procedures are carried out.
- Data collected in the Case Report Form (CRF) are supported by source documents (Hospital file or certified copy of Hospital file and Electric Medical Record (EMR).
- CRF entries should be made following the ALCOECCEA principle preferably within 7-10 working days from the day of the patient visit.
- Adverse events are reflected in the source documents and captured in the CRF. (With appropriate term, grade, causality, start and stop date and concomitant given if any.)
- Serious Adverse events (SAEs) are reported to the Sponsor/CRO and IEC within specified time frame (refer SOP for SAE reporting).
- The IP is will be dispensed as per the Protocol and IP accountability logs/inventory will be maintained.
- To ensure that the Study supplies remain adequate.
- Biological samples are being collected, processed, stored and shipped (if applicable) as per the institutional SOP and Sponsor manual. .
- If any study materials like CT scan, X ray, ECG recording etc., will be transferred in the manner described in the Sponsor's manual
- To check for the calibration of all study related equipment and maintain a record.
- Protocol deviations/non-compliance/violations/waivers if any should be notified to the IEC (Refer SOP for IEC communication) and the same must be documented in the source documents and appropriate CRF.
- SUSAR and CIOMS should be notified in the timely manner to the IEC.
- Track the expenses as per the budget agreed in CTA

- PI/study team to permit monitoring and ensure that all open action items from previous visits are addressed. If audit is planned the PI and his team should support in the conduct of the audit.

4.2 Premature Termination or Suspension of a Study

If the research study is prematurely terminated or suspended for any reason, the investigator/study team will:

- inform the IEC within 1 working day regarding the premature termination of the study in the format specified in the IEC SOP.
- PI will evaluate the participants enrolled in the study.
- If the study is terminated due to safety concerns, then the PI/study team will contact the enrolled patients and advise them to stop the study medication with immediate effect and report to the site at the earliest. Once the patient reports to the site, the PI/Co-I will examine the patient and carry out necessary investigations to ensure patient's safety. Alternative standard of care will be advised.
- If the study is discontinued for reasons other than safety, the PI/study team will discuss with the Sponsor about the continuation of the enrolled patients in the study and also discuss about post trial access about the enrolled patients. PI/study team will check the drug inventory and manage the unused/partly used IP as per the Sponsor manual/CTA (as applicable).
- The PI decides to terminate/suspend the research study due to any reason; the PI will inform the IEC and Sponsor (if applicable) along with the detailed reason for the decision regarding termination. The PI/study team will also make an action plan about the management of patients already enrolled in the study.

4.3 Applicable Staff

This SOP applies to

- Investigator
- Co-investigator
- CRC
- Research Nurse
- Any other Support staffs

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Study Close-Out

SOP Code: SOP 05/V1.1 **Date: 19/Jan/2022** **Pages: 34 to 35**

5.1 Site close-out

Preparing for a study close out

- The PI/study team will agree for a suitable date for the close out visit as per the Protocol specified last patient last visit.
- The PI and study team will review the ISF and ensure that all the essential documents are in place, al ICDs are available, CRF entries are complete, all open actin items from any monitoring report are closed and IP accountability is carried out.
- PI will inform the IEC about the study closure at the site.
- In case of sponsored studies, the PI/study team will confirm a suitable date with the CRA/Sponsor representative for conduct of a close out visit as per the agenda shared by the Sponsor.

The PI/study will make arrangements for archival of all study related documents.

5.2 Applicable Staff

This SOP applies to

- Investigator
- Co-investigator
- CRC
- Research Nurse
- Any other Support staffs

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Preparing an Informed Consent Document

SOP Code: SOP 06A/V1.1 Date: 19/Jan/2022 Pages: 36 to 38

6A.1 Purpose

- To describe the study specific information and essential elements (as per regulations) that should be included in the informed consent document (ICD) associated with research study. ICD consists of the Patient Information Sheet (PIS) and Informed Consent Form (ICF).

- To describe the procedure for obtaining voluntary informed consent from a prospective subject/participant for a research study and also to ensure that a subject's/participant's consent is sought in such a way that the subject/participant or his/her representative has ample opportunity to consider whether to participate in the study and under conditions that minimize the possibility of coercion or undue influence.

- To ensure that freely & voluntarily given written Informed Consent is obtained from each subject/participant in accordance with applicable regulatory requirement, NDCT Rules 2019, Indian GCP, ICMR/CDSCO guidelines, ICH-GCP and Declaration of Helsinki.

6A.2 Scope

This SOP will apply to all research studies conducted at the INSTITUTE where IC must be obtained.

6A.3 Procedure

6A.3.1 Preparing an Informed Consent Document

ICD should be available in English language and translated in the required local languages as per the Institutional requirements.

This ICD should be reviewed for all the required information in compliance with Protocol, NDCT 2019 Rules template/ICMR guidelines and IEC SOP.

Entire ICD should contain in English, a header of institute name and a footer with running page number, language of the ICD, Protocol version number and date, ICD version number and date.

Each ICD must contain the following on the first page:

Study title (full and short title),
Study number (if applicable)
Investigator name
Institute address
Participant name
Participant Date of Birth (DOB)/age

The ICD content should be as per the NDCT template.

The ICF should contain information about:

- The occupation of the participant

- Literacy status of the participant
- Annual income of the participant
- Name, address and contact number of the Nominee
- Name, address and contact number of the Participant

The ICF should have all the elements as specified in the NDCT rule ICD template.

The ICF should have space for name, signature and date of the:

- Participant
- Person administering the Consent
- Impartial Witness (if required during the Consent Process)

Refer to IEC SOP for any additional information required which can be included in the ICD.

Required translations with back translations and translation certificate should be available.

6A.3.2 Informed Consent Document (Assent Document) for Children:

In studies involving pediatrics population, an assent is required from certain age group besides an ICD signed by the Parent/Legal guardian.

This document is called an Assent form. This form should be available in English and necessary translations as required.

Assent form should be a short document explaining about the study in simple language, use of pictorial representation may be permitted for ease of understanding.

This form should ideally be of not more than 2 pages.

There should be space for the child to write his name, insert his signature and date.

This should be followed by the section for Investigator and the LAR to insert name, signature and date.

Entire Assent form should contain in English, a header of institute name and a footer with running page number, language of the Assent form, Protocol version number and date, Assent form version number and date.

Each Assent Form must contain the following on the first page:

- Study title (full and short title)
- Study number (if applicable)
- Investigator name
- Institute address
- Participant (Child) name
- Participant (Child)DOB/age

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Obtaining Informed Consent

SOP Code: SOP06B/V1.1 **Date: 19/Jan/2022** **Pages: 39 to 43**

6B.1 Purpose: To obtain Informed Consent from each participant. IC must be obtained prior to performing any study related procedure.

6B.2 Scope: This SOP will apply to all research studies conducted at the institute. This includes investigator initiated research as well as Pharma sponsored studies.

6B.3 Procedure:

6B.3.1 General procedure for obtaining Informed Consent from Participants:

The Principal Investigator will ensure that the IEC approved informed consent document/Assent form (PIS and ICF) is used for the Consent process.

The ICD used should be in the language in which the patient is able to read/write. In case a patient is fluent in multiple languages the ICD in the participant's primary language should be used. By primary language it means that the participant informs that he/she prefers to read/ write/communicate in that particular language.

The PI administers the IC to the participant. If the PI delegates the responsibility, it should be delegated to a medically qualified doctor of allopathic medicine and who has experience in administering consent. In case of studies where administering the IC by medically qualified personnel may not be feasible, a member of the research team can be delegated with the responsibility. However, this delegated person should be trained in the IC process and have experience in the administration of IC. There has to be documented delegation of this responsibility and the Protocol mentions so. This should be acceptable to the IEC during review. Such situations may arise in field trials/ basic research etc. The PI should obtain IEC approval for such consenting process.

The Investigator must explain all the elements of the ICD in the language the patient reads/writes and understand. The information should include

a. the experimental nature of the study
b. Purpose
c. Eligibility criteria
d. Investigations done
e. Treatment to be given
f. Known side effects of the treatment
g. The participation is voluntary and that the participant has a choice to withdraw the participation any time.
h. Contact details of the Investigator and the IEC.

The Investigator encourages the patient to ask questions and provides appropriate answers.

If the participant gives voluntary consent, all the details in the ICF(name/.address/DOB etc.) have to be completed by the participant. The ICF is then signed and dated by the participant and the Investigator.

A copy of this signed ICF is given to the participant.

All the elements described in the points above must be documented in the source document (patient's hospital file/EMR) have been approved by the IEC before they are used in a study and that the correct versions of the documents are used when the study is ongoing.

6B.3.2 Special circumstances:

Obtaining Informed Consent from illiterate participants:

An adult participant who speaks and understand a primary language but is unable to read/write in any language can be considered as an illiterate patient.

To consent an illiterate adult patient, the PI must ensure that an Impartial Witness (IW-who reads and writes the language the patient speaks) should be present throughout the IC process.

This IW must not be part of the study team or associated with the department in any capacity.

The PI to ensure that the IW who is present throughout the IC process reads out the entire IC process to the participant and communicates with the PI in case the participant raises any questions and relays the answers to the participant.

The details of the IW including his full name, contact information, literacy status would be documented in the ICF and the IC narrative. The illiterate patient will put a thumb impression in place of signature. The Date section will be left blank. The particular details of the participant in the signature page, first page and any other section (like name, address etc) would be entered by the IW.

After the thumb impression is inserted by the participant, the name, signature and date of the Investigator would be taken on the ICF followed by the IW.

The entire process would be documented in the source document as a detailed narrative.

The PI will ensure that the IW is not named as the nominee in the ICF.

PI could take the help of an interpreter who speaks/understand the language spoken by the patient and the Investigator.

An IW's signature on the ICF attests that the participant voluntarily agreed to participate in the study at the end of the entire IC process.

Obtaining Informed Consent from participants who are unable to consent (Minor/ mentally challenged/ semi-conscious/ unconscious /psychiatrically disturbed etc.)

For participants who are differently abled, the PI will approach the Legally Acceptable Representative (LAR) for the entire IC process using the IC document in the language the LAR reads and writes.

The Investigator must explain all the elements of the ICD in the language the LAR reads/writes

and understand. The information should include

a. the experimental nature of the study
b. Purpose
c. Eligibility criteria
d. Investigations done
e. Treatment to be given
f. Known side effects of the treatment
g. The participation is voluntary and that the participant has a choice to withdraw the participation any time.
h. Contact details of the Investigator and the IEC.

The Investigator encourages the LAR to ask questions and provides appropriate answers.

If the LAR gives voluntary consent, all the details in the ICF (name/.address/DOB etc.) have to be completed by the LAR. The ICF is then signed and dated by the LAR and the Investigator.

A copy of this signed ICF is given to the LAR.

LAR's signature authorized the enrollment of the participant in the study.

If the LAR is illiterate, all the process described above will be followed using an Impartial Witness.

Obtaining Informed Consent from Children:

For children between 0-7 years, only Parental consent would be taken.

For children between 7-12 years, a simple assent form which has been approved by the IEC will be used by the PI to explain verbally to the child about the study. The child's guardian would be present throughout the discussion. The Parent/Guardian will be administered the complete Informed Consent and the process for obtaining IC process would be followed.

For children between 12-18 years, an IEC approved Assent form would be used for discussion with the Child. The child will be allowed to ask questions and suitable answer would be given. Child's assent to participate would be documented by the Child entering the name, signature and date on the Assent form. The PI will also enter the name, signature and date followed by the legal guardian entering name/ signature and date. This will be followed by the entire IC process for the Parent/guardian.

The parent will fill in the details of the child in the ICD. A copy of the signed Assent from and Consent form would be provided to the guardian.

In case the LAR/guardian is illiterate, an assent form would be taken but an IW would be present throughout the IC process for the LAR/guardian.

Note: A child could refuse Assent to participate in a study. However, the PI would discuss the details with the Parents and the Parents could take a decision to overrule the child's refusal to participate. The reason for this decision would be documented in detail in the IC narrative.

6B.4 Reconsents would be administered in the following scenarios:

1. Improper IC process
2. Protocol amendment leading to IC amendment
3. A participant with mental incapacity regains full understanding (for example, a semiconscious patient becomes fully conscious)
4. During the course of the study, the child attains legal age for adult.

During Reconsent, the entire IC process as indicated above is applicable.

If the ICD is amended due to safety concerns, each participant would be explained about the concerns verbally and the same will be documented in a narrative till such a time the ICD is approved by the IEC. Once IEC approval is received, Reconsent would be administered.

6B.5 Applicable staff

This SOP applies to Investigator and the Co-Investigators.

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Audio Visual (AV) Recording of Informed Consent Procedure.

SOP Code: SOP 06C/V1.1 Date: 19/Jan/2022 Pages: 44 to 47

6C.1. Purpose:

- To describe the detailed procedure for recording, documenting, storage and archival of Audio-Visual (AV) Informed consent and assent process for regulated studies conducted in the institute.

- To ensure that Audio-Visual (AV) Informed consent is obtained from each potential subject/participant identified under regulated studies (wherever applicable), in accordance with New Drug Clinical Trial (NDCT) rules 2019.

6C.2.Scope:

a. This SOP will apply to all DCGI regulated studies (approved for AV consenting) being conducted in institute, which requires informed consents and assents procedures for participating in the studies.

b. This SOP will be applicable to all subject/participant planned to be enrolled in the regulated studies.

6C.3. Procedure:

6C.3.1. Procedures for Audio-Visual (AV) recording of Informed Consent process:

a) Requirement/Infrastructure for AV consent process recording

- For recording the Audio-Visual consent process, a room which gives privacy to the participant would have to be provided by the Investigator.

- The identified rooms are free from disturbances, and ideal to ensure that participants are comfortable and privacy & confidentiality is maintained.

- The room is equipped with camera at a distance where it can capture all the members involved in the consenting procedure.

- Investigator should ensure that faces of investigators, subject/ LAR/Impartial Witness and study team members involved in the consenting procedures are clearly visible in the recording frame.

- The voice recording device for recording the AV consenting procedures is rested on the hard platform which is free from vibration/any other disturbances.

- Before starting the actual consent procedure, Investigator should ensure that the devices are working properly.

- Investigator/Coordinator must ensure that there is enough memory/space before starting the recording process. The recoding will be stored in a system which can be accessed controlled and in the custody of the PI only.

b) Before AV Consent recording (Pre AV recording)

- Investigator/Coordinator/delegated study team member will ensure that the necessary infrastructure or requirements are in place and functional.
- Consent for AV recording will be taken before starting the AV process.
- Investigator will inform the participant that the AV recording is confidential and can be reviewed by ethics committee members, Regulatory authority Inspectors and in case of legal case.

c) During AV Consent recording

- The Consent process will begin with the Investigator identifying himself. He will also introduce other study team member if present in the room for example, CRC or photographer.
- The Investigator will request the patient to say his name. If there is a LAR or IW, they would also be requested to identify themselves by their name and role.
- PI will mention the study title, date and time of the IC process.
- In case the Investigator does not understand the language of the patient, he can be assisted by an interpreter.
- Once the patient voluntarily agrees to participate, all the relevant sections would be completed and the ICF would have been signed and dated by all the concerned parties.
- A copy of the signed and dated form would be handed over to the participant.
- Before concluding, the PI would thank the participant for their time and mention the date and the time when the process ended.

d) Post AV consent recording activities

- The entire recording would have to be saved in a secure computer/ CD or pen drive.
- The AV file should be patient specific and should have standardized nomenclature for identification. The same file will also be stored in the separate DVDs for respective patients and should contain the same nomenclature on the DVD.

E.g., the file can contain;

  - Patient screening no
  - Project no

  - Study protocol number (If any)
  - Date of consent
  - PI Name
  - Subject/participant Initial

- To maintain the confidentiality of the participants, The PI's PC should be encrypted using password protection.

- The DVDs/CDs/pen drive should be stored in a secure place.

- After the AV recording, the entire process must be documented in a detailed narrative in the source file or Electronic Medical Record (EMR).

6C.4. Applicable staff

This SOP applies the following personnel:

:

- Investigators
- CRC
- Photographer
- Any other team member.

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Recruiting and retaining study participants

SOP Code: SOP 07/V1.1 **Date: 19/Jan/2022** **Pages: 48 to 53**

7.1 Purpose

This SOP describes the procedures study team will use for recruiting eligible participants into a study as per the protocol /SOP/guidelines/applicable regulatory norms.

7.2 Scope

This SOP will apply to all clinical studies being conducted at the INSTITUTE.

7.3 Procedure

PI/study team will develop a recruitment plan/strategy to enroll participants in a study.

7.4 Recruitment strategies

Using the eligibility criteria for the study, the Investigator/study team or CRC will review records from the Investigator's patient population to determine the suitability and availability of candidates for the protocol. Patients will also be identified and screened for their eligibility during OPD or during joint clinic/tumour board discussion (as applicable).

The PI/study team will recruit patients from General and Private OPD (if applicable) to ensure equitable distribution of participants.

In case the institution has multiple locations, the PI will draw up an action plan of how the patients from multiple sites will be recruited including the person who will be responsible from each of the satellite sites and how the documents would be maintained at the primary site.

The PI will maintain the following logs:

a. Patient Screening log
b. Patient Enrolment log
c. Patient Identification log

These logs will be updated in real time.

Once the patient is recruited in the study, the Investigator will discuss with the CRC/research team to maintain visit log for the enrolled participants. This log would be customised as per the schedule of assessment visits detailed in the Protocol. This may be maintained as an excel sheet. This will assist the CRC to plan patient visits as per schedule.

7.5 Retaining study participants:

The CRC will call/message a participant 3-7 days before the scheduled visit. CRC will give

necessary instruction based on the type of visit (e.g., to come fasting if required, to make arrangements to stay overnight etc.) as applicable. In case a patient misses a visit, the PI/ study team will make at least 2 attempts to call the patient on the telephone number recorded in file. If the patient is still not reachable, the PI/study team will send registered Acknowledgement Due (AD) letter at the available address documented in the file. The details of the call/ letter will be documented in the patient file/EMR.

A participant will be declared as lost to follow up only after at least 2 telephone calls and 1 registered AD letter is sent to the participant.

7.6 Applicable staff

This SOP applies to

- Investigator
- Research Team (listed in the delegation log)
- CRC

AX1-V1.1/SOP 07/V1.1

Screening Log*

Study Title:
IEC project No/Protocol Number:
Sponsor Name (if applicable):
Principal Investigator:

Sr. no.	Date	Case No	Patient Initials	Screening Investigations/assessments done (Y/N)	Eligible for enrollment (Y/N)	Reason for screen failure	Remark

Subject to change as per protocol requirements

AX2-V1.1/SOP 07/V1.1

Enrolment Log*

Study Title:
IEC project No/Protocol Number:
Sponsor Name (if applicable):
Principal Investigator:

Screening No.	Trial ID/Enrolment No	Date of Consent	Case No.	Patient Initial	Trial Arm (if applicable)	Randomized by

Subject to change as per protocol requirements

AX3-V1.1/SOP 07/V1.1

Patient ID log

Study Title:
IEC Project No/Protocol Number:
Sponsor Name (if applicable):
Principal Investigator:

Name	Address	Contact detail	Hospital File number	Trial ID	Date of consent

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Source Documentation

SOP Code: SOP 08/V1.1 Date: 19/Jan/2022 Pages: 54 to 57

8.1 Purpose

This SOP defines the process and requirements related to the creation, maintenance and retention of all source documentation for the research studies conducted at INSTITUTE.

8.2 Scope

This SOP will apply to all clinical trials conducted at INSTITUTE.

8.3 Procedure

Source documents

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

All records (including written documents, electronic, magnetic or optical records, scans, x-rays etc.) that describe or record the methods, conduct and results of the study, and the actions taken. These include Protocol, copies of submissions and approvals from the office of the Drugs Controller General of India, ethics committee, investigator(s)' particulars, consent forms, monitor reports, audit certificates, relevant letters, reference ranges, raw data, completed CRFs and the final report.

Examples of source documents include, but are not limited to, the following:

- Patient's hospital case file & EMR
- Signed and dated Informed Consent Forms.
- Participants medical record or office charts.
- All treatment charts/protocol sheets/RT sheets
- Patient-specific correspondence which is retained in the medical record or office chart.
- Laboratory test results, requisition forms, and maintenance records.
- Films of x-rays, MRIs, CTs, and other diagnostic tests along with their interpretation and reports.
- ECG tracings and interpretations
- Patient diaries
- SAE Forms
- Data recorded directly onto the CRF if identified in the protocol or pre-study report as source data.
- Study worksheets if data is recorded that is not otherwise available in the medical record. Such worksheets should be preferably be on institutional Continuation Sheets and should be signed and dated by the PI/Co-I.

- In case the original Hospital file is not available as a source document, the CRC will photocopy all the relevant pages. These pages will be stamped, signed and dated by the PI/Co-I as certified true copies. This deviation of not having a patient's original file will be documented in a NTF and IEC to be informed.

- CRF is not a part of the source document. However, certain Protocols may specify about entries which can be directly made into the CRF, for example, assessment scales like Hamilton Depression scale, Physical activity questionnaire etc.)

- The source document would be signed by PI/CO-I. In case the CRC transcribes in the source document then the transcriber also signs and dates the document.

All entries in the CRF must be supported by data recorded in the source document, either as paper copies or EMR entries

PI and study team will apply ALCOACCEA* to achieve data quality.

- **A**ttributable: is it obvious who wrote it?
- **L**egible: can it be read?
- **C**ontemporaneous: is the information current and in the correct time frame?
- **O**riginal: is it a copy; has it been altered?
    - **A**ccurate: are conflicting data recorded elsewhere?
    - Complete: All paper or electronic data including original test results and examination findings must identify the person performing the examination/stoke test including the date when it was performed.
    - **C**onsistent: The data's sequence of events should be in the expected sequence of operations
    - **E**nduring: Paper or electronic data are appropriately recorded in laboratory notebooks or in validated software systems including spreadsheets and databases.
    - **A**vailable: Paper and electronic data are required to be readily available for review, audits, or inspections for the required lifetime of the record. Paper and electronic data should be clearly indexed and/or appropriately labeled to facilitate retrieval.

8.4 Source data

The source data that will be recorded will include (not limited too):

- Demographic data of the subject/participant (Name, Date of birth and Sex)
- Patient medical history, diagnosis, and medical follow up if any
- Concomitant medication, current and previous if any (with start and stop date)

- Detailed informed consent and randomization process
- Date of screening and randomization
- Participants screening and randomization number
- Randomization arm if applicable
- Protocol specific procedures
- Also mention if participants consented for the biological or genetic study (if any).
- In case of screen failure patients, investigator must document the reason for the same with sign and date.
- Safety data
- Efficacy data

Investigator and study team member (as per delegation log) can document the abovementioned information. Person documenting (as per delegation log) the information must sign and date the source note. All medical decisions must be taken by medically qualified study team member listed in the duty delegation log.

CRC will place a study identifier in the source file/EMR which will include at least the study title, study number (if available) and trial ID.

The PI/Co-I shall document that they have seen and reviewed the reports by signing and date in the hard copy of the report which is filed in the source document. CRC will take a print out of the same for signature.

The source document/EMR entries would be available to the monitors/ auditors/inspectors (as applicable) to facilitate source data verification. PI/CRC/research team to be make these available.

8.5 Applicable Staff

This SOP applies to
These include the following:

- PI/Co I
- Research Team (listed in the delegation log)
- CRC

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Archival of Documents

SOP Code: SOP 09/V1.1 Date: 19/Jan/2022 Pages: 58 to 60

9.1 Purpose

To describe the procedure of archiving documents during and at the end of the study at the institute

9.2 Scope

This SOP will apply to all clinical trials conducted at the INSTITUTE.

9.3 Procedure

The documents which need archival include:

1. Source documents for all the enrolled patients
2. Informed Consent Forms for all the enrolled patients
3. Investigator Site File
4. Any Biological material if collected during the course of the study
5. All films, tracings and CDs of all procedures. For example: PET CT/ CT scan films, PET CT/ CT scan in DICOME format, ECG tracing, Endoscopy films etc.

At the end of the study the PI will be responsible for archival of all the study materials.

For investigator initiated studies the document would be archived for a minimum period of 15 years after the submission of the complete study report to the Ethics Committee.

For Sponsored studies, the documents to be archived for 15 years or till the last marketing authorisation application made by the Sponsor. The PI will seek the approval of the Sponsor in writing before destruction of any archived study related material

All the documents will be archived in a secure, access controlled space. The Investigator will seek the support of the institute to archive in a place which is termite proof, water proof and fire proof. In case of a Sponsored study, the Sponsor may assist the Investigator to find a secure location to archive the documents.

Archival access log will be maintained mentioning specifically the personnel name and designations (study team members) for the access.

PI/CRC must record and retain the inventory AX4-V1.1/SOP 9/V1.1– Archive Inventory) record for future reference.

If the Principal Investigator leaves Institute, the head of the institute will be handed over the documents for both investigator initiated or sponsored study. The PI/CRC will inform the Sponsor about the change of custody of the documents.

9.4 Applicable Staff

This SOP applies to:

- Investigator
- Research Team (listed in the delegation log)
- CRC

AX4-V1.1/SOP 9/V1.1–
Archive Inventory

Study Reference Number	
Study Title	
Name of Sponsor	
Name of Principal Investigator	
Archival Date	
Archive Location	Onsite/Offsite/storage area
Archive Until	

Box Number 1	Contents
Box Number 2	

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Reimbursement

SOP Code: SOP 10/V1.1 Date: 19/Jan/2022 Pages: 61 to 62

10.1 Purpose

This SOP describes the procedures involved in reimbursement to the study participants for their participation in the research study. The reimbursement would be made as specified in Clinical Trial Agreement (CTA) and or Memorandum of Understanding (MoU) and detailed in mentioned in ICD. The reimbursement costs should be approved by the Ethics Committee.

10.2 Scope

This SOP applies to all study team members who are delegated with the responsibility of reimbursement to the research participant.

10.3 Procedure

Reimbursements may include the following:

1. Trial participants will be reimbursed for travel from residence to travel site and back for study specific visits only.
2. All study related procedure costs, for example-scans, biopsies, investigations etc.
3. Any study drug which may have to be purchased by the participant
4. Cost for a meal in the Hospital cafeteria in case the duration of the visit is during lunch time.

   All reimbursements would be against original bills which will be countersigned by the PI/Co-I and will include the participant's trial ID and study title/study number.

   The reimbursements may be made either directly to patient's Bank account or in cash as per the Hospital policy.

A ledger/document to be maintained with the participant's signature confirming receipt of the reimbursement.

10.4 Applicable Staff

- This SOP applies to Investigator
- CRC
- Research Team (listed in the delegation log)

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Training of Study Team

SOP Code: SOP 11/V1.1 **Date: 19/Jan/2022** **Pages: 63 to 64**

11.1 Purpose

This SOP defines the procedure of training the study team members for a particular study.

11.2 Scope

This SOP will apply to all study team members conducting studies in INSTITUTE. Minimum training will include:

a. Protocol
b. Indian GCP,
c. ICH GCP,
d. NDCT Rules
e. ICMR guidelines.

11.3 Procedure

Study Team Training

1. The Protocol specific training will be conducted by the PI/Co-I/Sponsor representative (as applicable). For Protocol training the PI/Sponsor representative will preferably conduct a face-to-face session for the entire study team

2. PI/Co-I/ Institutional Research Head /Sponsor/ Clinical Research Professional head will conduct training on the topics b-e listed above. The training may be conducted via classroom/ virtual platform/self- learning modules for topics b-e.

3. All the training imparted should be documented in a training log.

4. Any new member who joins the study team, would be trained on the Protocol/ regulations by the PI. He might take the assistance of the Sponsor representative.

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Handover of study responsibilities to another study team member

SOP Code: SOP 12/V1.1 **Date: 19/Jan/2022** **Pages: 65 to 69**

12.1 Study Handover

There are 2 scenarios where handover may be required:

1. When 1 study team member leaves the organization
2. When the study team member goes on a long leave (more than 1 month)

Prior to leaving the study, the existing study team member under the supervision of the PI/Co-I will complete the following handover procedure:

- Information regarding study participants, study documents and all study related activities, study related logs
- Outstanding data entry and/or data queries
- Training to complete source documents
- Explanation on the objectives & priorities
- All trackers
- Provide a list of study-specific contacts (e.g., sponsor, monitor, vendors involved etc.)
- ISF and IP inventory should be handed over to new person and same documented in a log.
- Provide a list of outstanding issues

PI will train the incoming person on the Protocol.

The PI will notify the IEC and Sponsor of the change in study team member. The PI will make the necessary changes in the signature and duty delegation log.

PI will check that all relevant documents have been handed over by the outgoing person to the incoming person.

If there is a change in PI, he will inform the Sponsor. IEC and institutional head about his decision to not be a PI on the study with an effective date.
The outgoing PI will hand over the necessary documentation and impart Protocol training to the new PI.
The duty delegation and signature log will be updated by both the PIs.
A hand over checklist may be prepared and signed by both the outgoing and incoming PI.

.

12.2 Applicable Staff

- This SOP applies to Investigator
- Research Team (listed in the delegation log)
- CRC

The following staff will be responsible for the handover activities:

- Investigators
- Co-Investigators
- CRC
- Research Nurse
- Pharmacist
- Other study team member
- Institutional Research Head.

AX1-V1.1/SOP12/V1.1

TRAINING Record

Department Name/Clinical Research unit _____

Name of Trainer:_____

Sr. No.	Date	Standard Operating Procedure Code	Trainee Initials	Trainee signature & Date

AX2-V1.1/SOP12/V1.1

Study Handover Log

Date of Handover	Topic covered	Name of study team member delivering handover	Dated Signature of handover delivering study team member	Name of study team member receiving handover	Dated Signature of handover receiving study team member	Dated signature of PI

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Clinical Research Pharmacy
A. Pharmacy Management
B. IP Management

SOP Code: SOP 13A/V1.1 Date: 19/Jan/2022 Pages: 70 to 94

Purpose:

To provide information on operational activities required by the Pharmacist to manage the Pharmacy.

This will include:

1. Setting up of a Pharmacy with availability of restricted access (with a swipe card/ledger documentation)
2. Temperature regulated environment
    a. To store at room temperature (25-30 C)-with a temperature logger
    b. To store at 2 to 8 C- walk in cooler
    c. To store at 15 to 20 C-with a temperature logger
    d. A freezer of -20 C and -80 C if applicable
3. A generator/UPS back up
4. Dedicated space to store quarantine drugs
5. Office space for the Pharmacist to carry out tasks
6. Workspace to withdraw, count study drugs before dispensing
7. Space to store returned/ used/ partly used study medication
8. Filing cabinets to store inventory records, temperature records, drug destruction records, correspondence with various departments/Sponsor
9. Alarm system to indicate temperature fluctuations

Scope:

This SOP applies to all CTN Pharmacy. It will therefore be applicable to all Investigators and research staff of the institute who will use the research pharmacy. This Research pharmacy will be under the responsibility and supervision of Institutional Research Head.

Procedure:

The CRS Pharmacy head will be responsible for the management of CRS Pharmacy and to ensure that the activities carried out by the Pharmacist is in compliance with SOP/ GCP and applicable regulations.

A. Pharmacy Management:

13A.1 Set up

1. Restricted Access:

Only the Pharmacist is permitted access to the Pharmacy. Any study team member who wishes to enter the Pharmacy should be accompanied by the Pharmacist. The access control will be documented in a ledger which should mandatorily include the following:

- Name and department of research staff
- Study title/number
- Time in and time out
- Signature of the Research Staff and Pharmacist/ Institutional Research Head

A separate ledger will be maintained to be maintained for any other Hospital staff wanting access to the Pharmacy. For example, electrical department. This ledger will contain the following information:

- Name and department
- Purpose
- Time in and time out
- Signature of the Staff and Pharmacist/ Institutional Research Head

Another ledger would be maintained for visitor wanting to access the Pharmacy, for example: Sponsor's Monitors/ Auditors; Regulatory Inspector, Ethics Committee Member, a Sponsor Representative during site evaluation visit etc.

This ledger will contain the following information:

- Name and Contact
- Name of the organization
- Purpose
- Time in and time out
- Signature of the Visitor and Pharmacist/Institutional Research Head

2 Temperature regulated cabinets:

- The cabinets for 2-8 degrees, 15-20 degrees, 25-30 degrees will have a 24 hour temperature logger installed.
- An alarm system will be installed to indicate fluctuations beyond permitted temperature
- Each of the cabinets will have access control which will be opened only by the Pharmacist.
- The Pharmacist will record the temperature in each of the cabinets twice a day on all working days. These temperature records will be maintained in a ledger which will include the following:

Time (AM): Maximum and Minimum temperature

Time (PM): Maximum and Minimum Temperature

Signature of the Pharmacist

- In case the 24 hours temperature logger data can be downloaded, then the Pharmacist will download and store this information.

- The logger and cabinet (if applicable) will be calibrated at least annually and a record maintained.

3. generator/UPS back up

These equipments will be checked and calibrated annually by the concerned department.

4. Alarm system to indicate temperature fluctuations:

- In case of excursions, an alarm will be set off in the Pharmacy. The pharmacist will immediately contact the Hospital electrical department to address the issue.

- On holidays/ weekends, the alarm will be set off in the Hospital security office. Upon being alerted, the security staff and or Institutional Research Head and Hospital Electrical department to address the issue.

- On the next working day, the details of the activity carried will be documented by the Pharmacist. If there have been temperature excursion, he will contact the study team members and ask for guidance on the management of the IP

13A.2. Cleanliness of the Pharmacy:

- The Pharmacy including all storage areas will be cleaned daily by a hospital allocated housekeeping staff.

- Housekeeping staff will use appropriate Protective gear as per the Hospital policy.

- The disinfectant floor mop solution will be as per the Hospital policy

- The Hospital staff who carries out the cleaning activity daily will sign of a activity sheet. The sheet should contain the name of the attendant, date, time and signature of the attendant and the Pharmacist.

- Cleaning of the storage and filing cabinets will be carried out by the respective research staff at the end of the use of the Pharmacy for the storage of IP.

- The Pharmacist will be responsible for maintaining cleanliness of his cabinet/work station.

B. IP management

13B.1 Purpose

To describe process for the receipt, storage, dispensing, return and destruction of Investigational Product (IP) at site.

13B.3 Scope

This Standard Operating Procedure (SOP) will apply to all research studies being conducted at the INSTITUTE.

13B.4 Procedure

13B.4.1 Prior to receipt of Investigational Product (IP)/ Study Drug

- PI will approach the Institutional Research Head, informing him about a study and its related IP and devices (if any) and request for the Pharmacy facility for the same.

This information will include at least the following:
Study title/number
Name of the IP
Storage condition of the IP
Quantity expected to be received
Duration
Devices (if any)
Name of the responsible research staff who will request access.

- The CRS head will authorize the same and inform the Research Pharmacist.

- The assigned study team member will collaborate with the Pharmacist and to identify a proper space as per the temperature requirement of the IP. The research staff will also inform the Pharmacist. The tentative date on which the consignment is expected to reach the Pharmacy will also be informed.

13B.4.2 Receipt of Investigational Product (IP)/ Study Drug

- Upon receipt of the IP shipment at the site, the Pharmacist in collaboration with the research team, will collect and check whether appropriate transit temperature has been maintained.

- If the temperature is appropriately maintained, the consignment would be opened and the following will be checked with the shipping note:

- The number of packs/kits

- The pack/kit number and batch number

- Subsequently the Pharmacist/research team will sign off the acknowledgement note with the delivery personnel and confirm the receipt of the shipment with the Sponsor along with the auto generated temperature logger.

- The receipt of the shipment will be documented in the accountability log and marked in the IWRS (if applicable)

- In case damaged packs have been received or the transit temperature have not been maintained, the further course of action will be discussed with the Sponsor/shipper. The steps taken would be documented.

13B.4.3 IP / Study Drug Storage

- The IP would be stored in the designated area (as per storage temperature specified in the Protocol) in the Pharmacy. The storage area can be labelled with the study identifiers like study short tile, name and contact details of the Investigator and the delegated research team member.

- Temperature would be recorded twice on working days and documented in the log.

- In case temperature excursion is identified, the delegated research team member would be informed about the same.

- The electrical department would also be informed about the breakdown and followed up for resolution.

- The handling of the drugs which has been exposed to temperature excursion/fluctuation will be as per the feedback from the Sponsor.

13B.4.4 IP / Study Drug Dispensing

- The Pharmacist will dispense the IP based on the allocation report produced by the delegated research team member.

- The dispensing will be captured in the drug inventory record. Tear off labels can be maintained with the allocation report (if applicable).

- The Pharmacist may update the research team member regarding the available stock (based on physical verification) to facilitate IP resupply.

- The CRC/research nurse can carry out all the IP related activities as per the duty delegation log other than dispensing provided the CRC/research nurse is trained.

13B.4.5 IP/ Study Drug Return

- The returned drug packs from the participants can be submitted to the Pharmacy by the delegated research team member.

- A separate log/inventory would be maintained for the returned packs.

- The returned packs will be handed back to the delegated research team member who would is required by the Sponsor or destroyed as per the Hospital policy.

13B.4.6 Return of IP to Sponsor

- When unused drug packs are to be returned to the Sponsor, the same can be collected by the delegated research team member from the Pharmacist.

- This will be documented in the drug inventory record.

13B.4.7 On-Site Destruction of IP

- The returned/ damaged/ expired drug packs would have to be destroyed as per the Hospital policy.
- The destruction activity can be taken up only after a written approval from the Sponsor is available.
- The Research Pharmacist will collect the required approval from the Institutional Research Head/ Bio medical waste management department (if applicable) and proceed with destruction process.
- The drug destruction certificate will be issued by the concerned department. The certificate will be filed in the Pharmacy records and provided to the research team for filing.

13B.5 Applicable staff

This SOP applies to:

Institutional Research Head

Pharmacist

Research Team Member (delegated for IP)

Support (House Keeping) Staff

AX1-V1.1/ SOP 13/V1.1

Drug Accountability Log

Project Title & Project No.:
Principal Investigator:
Drug /IP Name:

Sr. no.	Patient ID	Kit no./ Batch no	Date of Expiry	Quantity in stock	Date of dispensing	Dispensed by (Initial & sign)	Return Date	Quantity Returned	Received by(Initial & sign)	Remarks

AX2– V1.1/SOP13/V1.1
STUDY PRESCRIPTION FORMAT

Prescription No:-*(For Pharmacy Use only)* _____

Prescription Form
Protocol Number_____

Project No.: _____ **Date:**_____/_____/_____
DD / MM / YYYY

PI Name: _____ **INTERDISCIPLINARY TEAM:** _____

Rx (Only for Study Drugs)	**For Pharmacy Use Only**	
Drug	Batch Number	Quantity
Dispensed Date and Time:		
Authorized Prescriber's CC No. & Signature:	**Pharmacist's CC No. & Signature:**	

AX3– V1.1/SOP13/V1.1
STUDY DRUG LABEL

“For Clincal Study only”	
STUDY NO.:	Sponsor/Principal Investigator (in case of IIRs) NAME:
PArticipant ID:	Batch NO.:
Principle Investigator Name:	
DISPENSING DATE:???	
Expiry Date:	
Storage Condition	

AX4– V1.1/SOP13/V1.1
Clinical Research Secretariat

Subject- Permission to store study drugs in Clinical Research Pharmacy
Protocol No: -

Protocol Title: -

Principal Investigator: -
Respected sir

This is for your kind information that we have received the IEC approval for above mentioned study. As a part of this study, we will be receiving the study medications and this medication needs to be stored in a secure and temperature control environment as per protocol specifications.
Study product details and storage conditions are as follows

Sr.No	Drug Name	Quantity to be stored	Temperature requirement
1			
2			
3			

Please find the study IEC approval letter attached herewith for your kind perusal. Other essential documents softcopies as enlisted were sent to CRS pharmacy email. We will also submit the subsequent study amendments (if any).

Documents Enclosed

- IEC Approval Letter
- Prescriber Log

Following documents emailed to CRS Pharmacy

- IEC Approved Protocol
- Investigator Brochure
- Package Inserts

Kindly grant us the permission to store the drug in CRS pharmacy

Thank you and Regards

Authorized Signature and Date

AX5– V1.1/SOP13/V1.1
DRUG ACCOUNTABILITY LOG

PROJECT NO: PI NAME: DRUG NAME:

			DRUG ACCOUNTABILITY			DETAILS OF PERSON HANDLING THE DRUGS		
SR. NO.	DATE	INWARD	Participant ID	DISPENESED	STOCK AVAILABLE	NAME	DESIGNATION	SIGNATURE

AX6 – V1.1/SOP13/V1.1
TEMPERATURE RECORD

Site: Pharmacy; CRS
Temperature: Upto 25 Degree
Drug Stored: Study/Trial Drugs of studies under INTERDISCIPLINARY TEAMs
Month:

		Temperature (Degree Celsius)							
.	Date		Morning (°C)		Time	Evening (°C)		Name	Dated Signature
		Time	Min	Max		Min	Max		

Signature and Date of OIC, CRS: _____ Page ___ of ___

AX7 – V1.1/SOP13/V1.1
Clinical Research Pharmacy Signature & Delegation Log

Site Name:- Name of Institute

Clinical Research Head name	**Clinical Research Head Signature**	**Clinical Research Head Initials**	**Date From**	**Date To**

Print name (CC Number)	**Role***	**Signature**	**Initials**	****Tasks Delegated**	**From Date (dd-mmm-yyyy)**	**To Date (dd-mmm-yyyy)**	**Clinical Research Head and Date**

*Study roles can include but not limited to: **Pharmacist, Back-Up pharmacist, Delegated Team members**

PI Signature: (Sign once site closed):_____Date: _____

1.Study Drug Receipt	*2. Pharmacy Audit*	*3. Pharmacy Inventory software data entry*
4.Study Drug Order	*5. Record deviations/violations*	*6. Pharmacy Inventory software data quality check*
7.Study Drug accountability	*8. Communication with PI*	*9. Pharmacy Inventory software management and Troubleshoot*
10.Study drug dispensing	*11. Communication with Other concern Department*	*12. Pharmacy record maintenance*
13.Pharmacy Temperature recording	*14. Pharmacy Periodic Inventory and stock check*	

AX8– V1.1/SOP13/V1.1
Training Log

Protocol Title:_____ Date:_____

Name of The Pharmacist:_____ CC No: _____

Department: _____

Training Subject	Date	Comments

I have received and understood the safety and health training listed above and acknowledge that it has been given to me.

Pharmacist's Signature	Date	Supervisor's Signature	Date

AX9 – V1.1/SOP13/V1.1
CLEANING REPORT
(FOR WALK-IN COOLER)

QUARTER	DATE	TIME	NAME OF ATTENDANT	SIGN OF ATTENDANT	SIGN OF PHARMACIST
1					
2					
3					
4					

Signature and Date of OIC, CRS_____

AX10– V1.1/SOP13/V1.1
CLEANING REPORT
CABINETS & PHARMACY AREA

WEEK	DATE	TIME	NAME OF ATTENDANT	SIGN OF ATTENDANT	SIGN OF PHARMACIST
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
11					
19					
20					
21					
22					
23					
24					
25					
26					

Signature and Date of OIC, CRS_____

AX11– V1.1/SOP13/V1.1

Pharmacy Audit Tool

Instructions: List the protocol number, the date range that is being reviewed and the date of the review. Once the review begins, check √ the appropriate boxes for each question listed in the criteria section. When the review is completed for all applicable documents, the reviewer will sign and date the form. Use the comments section for clarification and action on any "no" entries checked.

Reviewed from (date)_____Through (date)_____

Document	***Criteria***	**Yes**	**No**	**N/A**
I.MAINTENANCE OF RECORDS				
A. Are the following documents present?	1. Drug Storage request letter with all necessary documents			
	2. Prescriber signature list and Pharmacy Duty Delegation log			
	3. Drug Accountability/ Inventory records			
	4. Drug shipment receipts/ Receipt emails			
	5. Temperature Log			
	6. Pharmacy Equipment calibration and Maintenance records			
	7. Pharmacist License and certificate , training records, GCP certificate			
	8. Drug Destruction records			
	9. Previous Internal Audit reports			
	10. Pharmacy Access / Visit tour records			
Comments/Problems				
C .Study Product specific Documents	*1.* Most recent version of the protocol for which the drugs are stored in pharmacy (Soft Copy)			
	2. . Most recent version of Investigators Brochure(s) ***(For pharma studies only)***			

Document	*Criteria*	Yes	No	N/A
	3. Most recent version of Package Insert(s) ***(For pharma studies only)***			
Comments/Problems				
III. SECURITY AND STORAGE OF THE INVESTIGATIONAL DRUGS				
A. Inspect the investigational drug storage area.	1. Are the investigational drugs stored according to the IEC approved protocol/ Manufacturer's specification?			
	2. Are expired stored / Used drug stored separately?			
Replace with'Is	3. Is study drug stored in a secure, limited access area?			
	4. Is Expired drug/Used drug stored for more than 90 days?			
Comments/Problems				
IV. DRUG ACCOUNTABILITY, PREPARATION AND DISPENSATION				
A. Accountability	1. Does entries made in Inventory log corresponds precisely with shipment receipts and prescription form?			
	2. Are the accountability records legible and complete with each entry signed by the authorized personnel?			
	3. Does drug accountability log present and completed?			
	4. Does the inventory balance documented on the accountability record correspond precisely with the actual physical inventory?			
	a. If No, provide actual numbers of the agent counted as well as the amount recorded on the accountability record for each discrepancy noted			
	Drug	**Accountability on Record**	**Inventory Amount**	**Remark**
Comments/Problems				

Document	*Criteria*		Yes	No	N/A
C. Prescription Review	1.Were any prescription reviewed during this assessment? If yes then Details :				
	Project No	**Visit Code**	**From Date**		**Through date**
Comments/Problems					
	1. Are the prescriptions signed by an authorized prescriber whose name appears on the study prescriber log?				
	2. If the dispensed study product and the quantity dispensed, has a corresponding entry been made in the Accountability Log?				
	3. Are the prescriptions and/or Accountability Records legible and complete with each entry initiated by authorized personnel?				
Comments/Problems					
V. Inventory Management Software					
	1. Does timely entries were done in Pharmacy Inventory management software?				
	2. Does entries made in software correspond with hard copies of Inventory and dispensing logs?				
	3. Does pharmacy software data is secure and available to only authorize personnel.				
	4. Does pharmacy software has valid audit trails for corrections made in entries?				
	5. Does software data backup is available? Please specify how often the data backup took place.				
	6. Does any updates of modification done in software since last visit. If yes Does Software update/ Change report is available?				

Document	*Criteria*	Yes	No	N/A
Comments/Problems				

Comments/Corrective action to follow up on any "no" entries:

Problem	Corrected by/date

Reviewer
Sign and Date

OIC, CRS
Sign and Date

AX12– V1.1/SOP13/V1.1
PHARMACY VISIT RECORD

Date:_____

INTERDISCIPLINARY TEAM:_____ PI

Name:_____ Project No.:_____ Study

Short Name:_____

Visitor's Name:_____

Designation:_____

Name Of Organization:_____

Purpose Of Tour:

- ☐ Site Initiation Visit
- ☐ Site Monitoring
- ☐ Site Audit
- ☐ Site Inspection
- ☐ Study Closed-Out Visit
- ☐ Other,

Suggestion (If Any):_____

_____

Is Information/Intimation Done A Day Before The Tour? (Y/N):
(Note: The Pharmacy Tour Will Be Forbidden If Not Inform Prior)

_____ _____
Signature of Visitor Signature of Study Team Member

_____
Signature of Research Pharmacist

AX13– V1.1/SOP13/V1.1
Quarantine Log

Study Name/Number	Noted Temperature excursion	Duration	Quarantined Yes/No	Informed the study team Yes/No	Response from sponsor/study team received (Yes/No	Action taken (Destruction according to protocol/permission for use)

AX14– V1.1/SOP13/V1.1
Log for Calibration Certificate Document of the Equipment

Equipments listed	Date of Caliberation	Renewal date of caliberation	Request to be sent for renewal (date – 1 month prior to renewal date)	Validated Certificate Present/Absent

AX15-V1.1/SOP 12/V1.1
Drug accountability diary (for Participant)

Sr. No.	Date	Number/ Quantity of IP taken	Drugs consumed (Yes/No)	Remark/reason if IP was missed

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Essential Documents

SOP Code: SOP 14/V1.1 Date: 19/Jan/2022 Pages: 95 to 115

Essential Documents for Conduct of Clinical Trial (Adapted fromE6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Kindly refer for more details)

A) Before the Trial Commence

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Located in Files of	
			Investigator /Institution	Sponsor
1	**INVESTIGATOR'S BROCHURE**	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
2	**SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)**	To document investigator and sponsor agreement to the protocol/amendment(s)and CRF	X	X
3	**INFORMATION GIVEN TO TRIAL SUBJECT** **-INFORMED CONSENT FORM** (including all applicable translations)	To document the informed consent	X	X
	-ANY OTHER WRITTEN INFORMATION	To document that participants will be given appropriate written information (content and wording)to support their ability to give fully informed consent	X	X
	-ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive	X	

4	**FINANCIAL ASPECTS OF THE TRIAL**	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
5	**INSURANCE STATEMENT** (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X
6	**SIGNED AGREEMENT BETWEEN INVOLVED PARTIES,**e.g.: – Investigator/institution and sponsor – Investigator/institution and CRO – Sponsor and CRO – Investigator/institution and authority (ies) (where required)	To document agreements	 X X X	 X X (where required) X X

7	**DATED, DOCUMENTED APPROVAL/FAVORABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB)/INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:** • Protocol and any amendments • CRF (if applicable) • Informed consent form(s) • Any other written information to be provided to the subject(s) • Advertisement for subject recruitment (if used) • Subject compensation (if any) • Any other documents given approval/favorable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favorable opinion. To identify the version number and date of the document(s)	X	X

8	**INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION**	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
9	**REGULATORY AUTHORITY(IES)AUTHORIZATION/APPROVAL/NOTIFICATION OFPROTOCOL** (where required)	To document appropriate authorization/approval/notificatio nn by the regulatory authority (ies)has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
10	**CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR (S) ANDSUBINVESTIGATOR (S)**	To document qualifications and eligibility to conduct trial and/or provide medical supervision of participants	X	X
11	**NORMAL VALUE (S)/RANGE (S) FOR MEDICAL/LABORATORY/TECHNICAL PROCEDURES (S) AND/OR TEST (S) INCLUDED IN THE PROTOCOL**	To document normal values and/or ranges of the tests	X	X
12	**MEDICAL/LABORATORY/TECHNICALPROCEDURES/TESTS** – Certification or – Accreditation or – Established quality control and/or external quality assessment or – Other validation (where required)	To document competence of facility to perform required test(s), and support reliability of results	X (where required)	X

13	**SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)**	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the participants		X

14	**INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator's Brochure)**	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational product(s) and trial-related materials	X	X
15	**SHIPPING RECORDS FOR INVESTIGATIONALPRODUCT(S) AND TRIAL-RELATED MATERIALS**	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	X	X
16	**CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED**	To document identity, purity, and strength of investigational product(s)to be used in the trial		X
17	**DECODING PROCEDURES FOR BLINDEDTRIALS**	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining participants' treatment	X	X (third party if applicable)
18	**MASTER RANDOMIZATIONLIST**	To document method for randomization of trial population		X (third party if

				applicable)
19	**PRE-TRIAL MONITORING REPORT**	To document that the site is suitable for the trial (may be combined withA.20)		X
20	**TRIAL INITIATION MONITORING REPORT**	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (maybe combined with A.19)	X	X
21	**SITE STANDARD OPERATING PROCEDURE**	The site should have detailed SOP before trial initiation	X	X (if applicable)

a) During the Clinical Conduct of the Trial

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

	Title of Document	Purpose	Located in Files of	
			Investigator /Institution	Sponsor
1	**INVESTIGATOR'SBROCHUREUPDATES**	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X
2	**ANY REVISIONTO:** - Protocol/amendment(s)and CRF - Informed consent form - Any other written information provided to participants - Advertisement for subject recruitment (if used)	To document revisions of these trial related documents that take effect during trial	X	X

3	**DATED, DOCUMENTED APPROVAL/FAVORABLEOPINION OF INSTITUTIONAL REVIEW BOARDIRB)/INDEPENDENT ETHICS COMMITTEE (IEC)OFTHEFOLLOWING:** • Protocol amendment(s) • Revision(s)of: — Informed consent form — Any other written information to be provided to the subject — Advertisement for subject recruitment (if used) • Any other documents given approval/favorable opinion • Continuing review of trial (where required)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s).	X	X

4	**REGULATORY AUTHORITY(IES) AUTHORIZATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR:** • Protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	X (Where required)	X
5	**CURRICULUM VITAE FOR NEWINVESTIGATOR(S) AND/OR SUBINVESTIGATOR(S)**	(SeeA.1)	X	X
6	**UPDATES TO NORMAL VALUE(S)/RANGE(S) FORMEDICAL/LABORATORY/TECHNICALPROCEDURE(S)/TEST(S) INCLUDED IN THEPROTOCOL**	To document normal values and ranges that are revised during the trial(seeA.11)	X	X
7	**UPDATES OF MEDICAL/LABORATORY/TECHNICALPROCEDURES/TESTS** – Certification or – Accreditation or – Established quality control and/or external quality assessment or – Other validation (where required)	To document that test, remain adequate throughout the trial period(seeA.12)	X (Where required)	X
8	**DOCUMENTATION OF INVESTIGATIONALPRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT**	(SeeA.15)	X	X
9	**CERTIFICATE(S) OF ANALYSIS FOR NEWBATCHES OF INVESTIGATIONAL PRODUCTS**	(SeeA.16)		X
10	**MONITORING VISIT REPORTS**	To document site visits by, and findings of, the monitor		X

11	**RELEVANT COMMUNICATIONS OTHER THANSITEVISITS** - Letters - Meeting notes - Notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE)reporting	X	X
12	**SIGNEDINFORMEDCONSENTFORMS**	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also, to document direct access permission (see A.3)	X	
13	**SOURCE DOCUMENTS**	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	X	
14	**SIGNED, DATED, AND COMPLETED CASE REPORT FORMS(CRF)**	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded	X (copy)	X (original)
15	**DOCUMENTATION OF CRF CORRECTIONS**	To document all changes/additions or corrections made to CRF after initial data were	X (copy)	X (original)

		recorded		
16	**NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS**	Notification by originating investigator to sponsor of serious adverse events and Related reports.	X	X

17	**NOTIFICATION BY SPONSOR AND/ORINVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION**	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions and of other safety information in accordance.	X (where required)	X
18	**NOTIFICATION BY SPONSOR TOINVESTIGATORSOFSAFETY INFORMATION**	Notification by sponsor to investigators of safety information.	X	X
19	**INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)**	Interim or annual reports provided to IRB/IEC and to authority (ies).	X	X (where required)
20	**SUBJECT SCREENING LOG**	To document identification of participants who entered pre-trial screening	X	X (where required)
21	**SUBJECT IDENTIFICATION CODE LIST**	To document that investigator/institution keeps a confidential list of names of all participants allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	

22	**SUBJECT ENROLMENT LOG**	To document chronological Enrolment of participants by trial number	X	

23	**INVESTIGATION PRODUCTS ACCOUNTABILITY AT THE SITE**	To document that investigational product(s)have been used according to the protocol	X	X
24	**SIGNATURE SHEET**	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs	X	X
25	**RECORD OF RETAINED BODY FLUIDS/TISSUES AMPLES (IF ANY)**	To document location and identification of retained samples if assays need to be Repeated	X	X

b) After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified in Sections8.2 and 8.3 should be in the file together with the following

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	Sponsor
1	**INVESTIGATIONAL PRODUCT(S)ACCOUNTABILITY ATSITE**	To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product (s) received at the site, dispensed to participants, returned by the participants, and returned to sponsor	X	X
2	**DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION**	To document destruction of unused investigational products by sponsor or at site	X (If destroyed at site)	X
3	**COMPLETED SUBJECT IDENTIFICATION CODE LIST**	To permit identification of all participants enrolled in the trial incase follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
4	**AUDIT CERTIFICATE** (if available)	To document that audit was performed		X

5	**FINAL TRIAL CLOSE-OUT MONITORING REPORT**	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X

6	**TREATMENT ALLOCATION ANDDECODINGDOCUMENTATION**	Returned to sponsor to document any decoding that may have occurred		X
7	**FINAL REPORT BY INVESTIGATORTO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THEREGULATORYAUTHORITY(IES)**	To document completion of the trial	X	
8	**CLINICALSTUDYREPORT**	To document results and interpretation of trial	X (If applicable)	X

AX2-V1.1/SOP 14/V1.1

Contents of Site Master File

Sr. No.	Content
1.	**Contact details-**
	5. Contact detail of Principal Investigator, Co- Investigator, Clinical Research Coordinator, Research Nurse etc.
	5. Signed and dated CV, MRC, GCP certificate of PI, Co-I and other site research Staff
2.	**Agreements-**
	A. Confidentiality Disclosure Agreement (CDA)
	B. Clinical Study Agreement (CSA)/Clinical trial Agreement (CTA)
	C. Financial Disclosure Form (FDF) If Applicable
	D. Material Transfer Agreement
	Finance
	A. Grant offer letter
	B. Payments of investigator sponsor
	C. Accounts statement/ Utilization Certificate
	D. Expense statement for Investigators Meeting
	E. Payments to other sites
3.	**Insurance-**
	A. Insurance Policy
	B. Other documents
4.	**Ethics Committee-**
	A. Composition of ethics committee, EC SOP
	B. Submission letter/Notification
	C. Approval letters
	D. Annual/Interim Progress report
	E. Other communication
5.	**Major Documents related to conducting of the trial**
5.1	**Protocol**
	A. Current approved protocol
	B. Protocol Signature Page
	C. Amendments (If Any)
5.2	**Investigational Brochure (IB)**
	A. Current approved Investigational Brochure
	B. Amendments (If Any)
5.3	**Informed Consent Form (ICF)**
	A. Current EC approved version of ICF with translations in other vernacular Languages
	B. Assent form (if applicable)
	C. Translation and Back translation certificates
5.4	**Case Report Form (CRF)**
5.5	**Laboratory Related Documents**
	A. MoU with an outsourced laboratory

	B. NABL Accreditation
	C. Normal laboratory ranges
5.6	**Miscellaneous**

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Safety Reporting

SOP Code: SOP 15/V1.1 Date: 19/Jan/2022 Pages: 116 to 125

15.1. Purpose:

To describe the procedure of safety reporting of all the studies undertaken at the institute.

15.2. Scope:

This SOP would be followed while evaluating safety reports timelines and norms as per NDCT Rules 2019 and ICMR guidelines 2017.

15.3. Applicable to whom:

The SOP would be applicable to the Investigators/sub-Investigators/ CRC involved in patient management and safety reporting.

15.4. Procedure:

15.4.1. The PI will train other Co-Is and team members regarding safety reporting norms in NDCT Rules 2019, ICMR guidelines 2017 and Indian GCP guidelines 2002.

The PI will familiarize the team with CTCAE (version as specified in the Protocol) terminology.

15.4.2.1. Definition:

Adverse Events:
An **adverse event** (**AE**) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

Examples of Adverse Event include but are not limited to:

- Abnormal test finding
- Clinically significant symptoms and signs
- Changes in physical examination and findings
- Hypersensitivity
- Drug abuse
- Drug dependency
- Additionally, AE may include the signs or symptoms resulting from:
- Drug overdose,drug withdrawal, drug misuse, drug interactions, exposure during pregnancy.

15.4.2.2. During the study conduct, the following details related to the AE would be captured in the source document and CRF:

(a) AE term
(b) CTCAE Grade
(c) Start date and stop date
(d) Causality Assessment:
Expectedness
Relatedness

(e) Concomitant medications (used to treat the AE)

15.4.3.1. Definition:

Serious Adverse Event:

A **Serious Adverse Event** (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose:

1. results in death,
2. is life-threatening
3. requires inpatient hospitalization or causes prolongation of existing hospitalization
4. results in persistent or significant disability/incapacity,
5. is a congenital anomaly/birth defect, or
6. important medical events that may not result in death, be life threatening, or require hospitalisation may be considered serious when , based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Note:

- Life threatening: refers to an event in which the participant is at risk of death at the time of the event; it does not refer to an event that hypothetically might cause death if it were more serious.
- Hospitalization: The Protocol will specify criteria of admission.
- The Protocol will specify whether death due to disease progression or events after the subject have completed study schedule and or survival follow up would be reported to the concerned authorities

15.4.3.2. When to report:

The Protocol would define the reporting period of SAEs. The active reporting period begins from the time the participant provides Informed Consent, through and including 28 days after the last administration of the IMP or longer depending upon the Investigational Medicinal Product under investigation. SAEs which are causally related can be reported after the active reporting period.

15.4.3.3. The PI/Co-I will follow the following steps while reporting SAEs:

For regulated studies:

(a) Whether the event can be considered as SAE as per the described criteria above.

(b) SAE for sponsored studies to be reported to IEC, CDSCO, Sponsor, Head of the Institute as applicable within 24 hours of occurrence using the template in the NDCT rules 2019.

(c) A detailed report with due analysis by the PI to IEC, CDSCO and Institute Head within 14 days from the occurrence of the SAE.

(d) PI/Co-I/CRC will ensure that the SAE would be captured in SAE form/ source document (paper/electronic) and CRF in a consistent manner.

(e) The PI will communicate with the Sponsor about payment of medical management and compensation as applicable.

(f) PI/study team will ensure that the medical management is free of to the participant and compensation is paid to the participant/nominee.

For Investigator Initiated studies:

a. SAE to be reported to IEC and Sponsor Principal Investigator (if applicable) within 24 hours of occurrence.

b. Follow up report with due assessment to IEC and Sponsor PI (if applicable) within 14 days.

c. Medical management and compensation to be paid as per the ICMR guidelines.

The timelines and the stakeholders involved in safety reporting for regulated studies are as follow:

Stakeholders	IEC	Head of the Institute	CDSCO	Sponsor
Investigator**:** 24 hrs of occurrence of SAE (initial report)	√	-	√	√
Investigator: 14 calendar days occurrence of SAE (detailed report with causality assessment)	√	√	√	-

The timelines and the stakeholders involved in safety reporting for investigator-initiated studies are as follow:

Stakeholders	IEC	Sponsor-Principal Investigator (if applicable)
Investigator**:** 24 hrs of occurrence of SAE (initial report)	√	√

Investigator: 14 calendar days occurrence of SAE (detailed report with causality assessment)	√	√

15.5 Applicable Staff

This SOP applies to all the personals of the clinical research team who may be responsible for reporting SAE.

These include the following:

- Investigator
- CRC
- Research Team member(s)

Annexure 1/V1.1/SOP 15/V1.1

SAE Report Template-For Investigator Initiated Studies

SERIOUS ADVERSE EVENT REPORT	**Regulated by DCGI: Yes / No** **CTRI Reg. No:**

As per ICH-GCP:

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose that:

- **Results in death,**
- **Is life-threatening,**
- **Requires inpatient hospitalization or prolongation of existing hospitalization,**
- **Results in persistent or significant disability/incapacity,**
- **is a congenital anomaly/birth defect**
- **important medical events that may not result in death, be life threatening, or require hospitalisation may be considered serious when , based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.**

Investigator(s) shall report all SAE's including Death to the IEC, Sponsor-Investigator,CDSCO and within 24 hours of their occurrence of the knowledge of the PI. If a delay is expected kindly notify the same by email.

1.	Title of project:
2.	Principal Investigator:
3.	Report Date : Report Type : □ Initial □ Follow-up_____If Follow-up report, State Date of Initial report_____ □ Final_____If Final report, State Dates of Initial/Follow up report_____
4.	Date of Occurrence of SAE :
5.	Subject Case No : Subject Trial ID : Date of Birth : Height: Weight: Gender : □ Male □ Female

6.	Study Arm to which subject is randomized : □ Test □ Standard Arm □ NA
7.	Mention the total number of SAE (prior) occurred at this site: _____ Other site(s): _____
8.	Mention number of similar SAEs (prior) occurred for same study at this site :_____ Other site(s) : _____
9.	A] State SAE Event term: B] CTCAE Grade : (Kindly refer to CTCAE V4.03 where applicable) (where applicable)
10.	Does the Principal Investigator feel this SAE is related to participation in the trial? □ Yes □ No Principal Investigator to provide justification for causality assessment:
11.	Tick whichever is applicable for serious adverse event: (Kindly note that this refers to IP/intervention being evaluated and NOT disease process) A] □ Expected Event □ Unexpected Event
	B] □ Hospitalization □ Increased hospital stay □ Death □ Others In case of Death, state probable cause of death _____ (If others, please specify):
	C] □ No permanent significant functional/ cosmetic impairment □ Permanent significant functional/ cosmetic impairment □ Not applicable
12.	The cost of treatment/hospitalization was borne by, □ Patient □ Institute □ Sponsor/CRO
Drug information (refers to drug/ device/ procedure under investigation)	
13.	IP/ Placebo (include generic name)/device/intervention: Generic Name: Indication:
14.	Dose: Dosage Form:
15.	Route(s) of administration:
16.	Therapy Dates: Start Date: Stop Date:
17.	Therapy duration:
18.	Was study intervention discontinued due to event? □ Yes □ No
19.	Did the reaction decline after stopping the drug / procedure (De-challenge & Re-challenge information) □ Yes □ No □ NA

<table>
<tr><th colspan="2">Concomitant drugs and history (drugs that the patient maybe on)</th></tr>
<tr><td>20.</td><td>Concomitant drug(s) including OTC drugs and date of administration:

Non-drug therapies (if any):</td></tr>
<tr><td>21.</td><td>Patient relevant history (e.g. diagnosis, allergies):

(Tick in the applicable box) (This is applicable only for regulated clinical trials)
R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:
a) 0.5 Terminally ill patient (expected survival not more than (NMT) 6 months) □
b) 1.0 Patient with high risk (expected survival between 6 to 24 months) □
c) 2.0 Patient with moderate risk □
d) 3.0 Patient with mild risk □
e) 4.0 Healthy Volunteers or subject of no risk □</td></tr>
<tr><td colspan="2">SAE Details</td></tr>
<tr><td>22.</td><td>Description of serious adverse event including follow-up information also.</td></tr>
<tr><td>23.</td><td>Describe the medical treatment provided (if any) to the research subject: This is an update on treatment given during hospitalization and /or used for management of the SAE.

<table>
<tr><th>Medication</th><th>Dose</th><th>Start date</th><th>Stop date</th></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table>

De-challenge and re-challenge information (if any):</td></tr>
<tr><td>24.</td><td>Outcome was □ Resolved □ Ongoing □ Death
In case of death please mention cause of death, post mortem findings (if any) and its possible relationship to suspected event.</td></tr>
<tr><td>25.</td><td>Was the research subject continued on the research protocol?
□ Yes □ No □ NA (Mark ‘NA’ in case of death)</td></tr>
<tr><td>26.</td><td>What phase of the research protocol is the patient in?
□ On active treatment
□ Short term follow-up
□ Long term follow-up
□ Surveillance/ Monitoring</td></tr>
</table>

27.	In your opinion, does this report require any alteration in trial protocol? □ Yes □ No If yes then please specify. Name of Principal investigator: Address of the PI: Contact No. of PI: _____ Signature of Principal investigator _____ Date: _____

Annexure 2/V1.1/SOP 15/V1.1

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL AS PER NDCT RULES 2019

1. Patient Details: Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc) Gender Age or date of birth Weight Height

2. Suspected Drug(s) : Generic name of the drug* Indication(s) for which suspect drug was prescribed or tested. Dosage form and strength. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg). Route of administration. Starting date and time of day. Stopping date and time, or duration of treatment

3. Other Treatment(s): Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Serious Adverse Event: Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event* Start date (and time) of onset of event. Stop date (and time) or duration of event. De-challenge and rechallenge information. Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings. Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator* Name and Address Telephone number Profession (specialty) Date of reporting the event to Central Licensing Authority: Date of reporting the event to ethics committee overseeing the site: Signature of the Investigator or Sponsor.

Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Clinical Trial Agreement (CTA)

SOP Code: SOP 16/V1.1 **Date: 19/Jan/2022** **Pages: 126 to 133**

16.1 Purpose

- This Standard Operating Procedure (SOP) describes the procedure which has to be followed during the preparation, review, acceptance and execution of the Clinical Trial Agreement (CTA by the Institution and/or Principal Investigator and collaborators (e.g.-Sponsor/CRO etc.)
- This SOP is in place to ensure that both, Institute and the Principal Investigator (PI), have all the necessary aspects covered as applicable to their specific project.

16.2 Scope:

This SOP will apply to all the trials where there is an extramural collaboration like industry sponsored trails as well as Investigator Initiated Trials receiving funding/support from any source.

16.3 Procedure

16.3.1. Preparation of the CTA:

The Following elements may be included in the CTA:

Part A:
Details of the parties
Background
Effective date
Agreed terms:

a. Definition
b. Responsibilities of the Sponsor
c. Responsibilities of the PI
d. Responsibilities of the Institution
e. Study drugs and Materials
f. Study documentation
g. Monitoring and Audit by the company
h. Inspection by regulatory authorities
i. Payments
j. Intellectual property
k. Confidential information
l. Personal data and biological information
m. Rights to publication
n. Insurance and indemnity
o. Compliance, transparency, anti-bribery, anti-corruption and conflicts of interest
p. Term and termination
q. Jurisdiction and Governing Laws
r. Others/General

Part B: Detailed budget

Part C:
Recruitment targets
List of materials provided by the company
Materials provided by the site
Source data, records and storage

16.3.2. Review of draft CTA

The PI and institute to review the CTA as per the institutional policy. PI to check that all the elements of CTA mentioned in the preparation section have been included. .

CTA can be several types depending on the number of stakeholders involved. They are:

Sr.No	Types of CTA	Description	Example
1	Bipartite	Involvement of two parties	Funding agency and the PI.
2.	Tripartite	Involvement of three parties	Between a sponsor/CRO, the Institute and the Principal Investigator

16.3.3. Acceptance and Execution of the CTA:

After the CTA elements have been reviewed and finalized by the concerned parties, it should be signed off.
Apart from the signature page, preferably all the pages may be initialed (in the footer) by the parties.

The number of original copies of the CTA would depend on the number of stakeholders.
The copy of the signed CTA would have to be submitted to the Institutional Ethics Committee (modifiable according to institutional policy).

16.3.4. Addendum to the CTA

During the study conduct, in case any existing clauses needs to be modified, the same has to be agreed upon by all the parties in writing. The addendum can be signed off and notified to the IEC.

16.3.5. For Academic trials:

Site should have signed CTA/MoU/MTA (Material Transfer Agreement)/other agreements for all Investigator Initiated trials or Sponsor-Investigator Initiated trials as applicable.

Annexure 1: Template for reference.

16.4 Applicable staff

This SOP applies to all members of the clinical research team involved in the process of finalizing the Clinical Trial Agreement at site. These include the following:

- Principal Investigator
- Legal Expert /CRS head/ departmental head (as per institutional policy)
- Institution Head
- Sponsor/External Collaborator

Annexure 1/**V1.1/SOP 16/V1.1**:

"Academic clinical trial" means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licensing Authority or regulatory authority of any country for marketing or commercial purpose;

(New Drugs & Clinical Trial Rules, March 2019)

MEMORANDUM OF UNDERSTANDING

This MOU is made effective as of the [number] day of [month], [year] (the "Effective Date"), and is by and among

PARTIES

(1) **[PHARMACEUTICALS and/ DEVICE/SPONSOR company]** referred to as Company incorporated in India, whose registered office is at :<> ("the Company")

(2) **"INSTITUTE"** is an_____body owned, funded and controlled by the _____ having its address at_____; and

(3) <>is employed by "INSTITUTE" at "ADRESS OF THE INSTITUTE" ("the Principal Investigator)

Together the "Parties" and each a "Party".

Project details:

Project title: "<>"

Investigators/Location :< Investigator Name>< Institute Name>

Principal Investigator: <Name>

Terms and Conditions:

In consideration of the clauses contained in this document, the parties hereby acknowledge and agree on the following terms and conditions:

Section 01: Site

1.1 This study will be submitted for the approval by Institutional Ethics Committee of "INSTITUTE". The study protocol has been attached herewith for your ready reference.

1.2 The study shall be performed under the direction and supervision of the Principal Investigator (PI). The study shall be conducted in accordance with the approved research protocol and applicable guidelines and regulatory requirements.

1.3 The PI should make available adequate facilities, including the Study Site, equipment and any other resources that are reasonably required to appropriately follow the Protocol.

1.4 Principal Investigator shall obtain the informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Document and in accordance with Applicable Laws.

1.5 The Serious Adverse Event reporting and follow up would be as per the regulatory and IEC SOP requirements, which shall be duly complied with by the Principal Investigator/Co-Investigators.

1.6 The PI will permit IEC and IEC appointed team to monitor the study from time to time.

1.7 The grounds for premature termination/ closure of the research study and relevant communications would be notified by the PI to the site IEC.

Section 02: Finance and Research Grant NA ☐

(If there is no monetary grant being provided, Please tick) NA in the box)

A research grant for supporting research by the PI/Institute will be provided by the Pharmaceutical or device company on the following terms and conditions:

2.1 On the receipt of appropriate approvals for initiation of the study the sanctioned cost of Rs (in figures) (in words) would be released as a one-time grant by the Pharmaceutical and or device/Sponsor company.

2.1.1 The grant which is released for research purposes only and shall be utilized by PI/Institute for which it is sanctioned.

2.1.2 An audited certificate of proper utilization of the funds granted will be obtained by the PI and submitted to the IEC

2.2 The Principal Investigator is accountable to the Institute and IEC for proper utilization of allocated funds. Appropriate record of fund utilization must be maintained and IEC/Institute reserves the right of auditing the accounts.

2.2.1 The Principal Investigator shall maintain and submit to the IEC during the Continuing Review Application (CRA) submission, the following record with respect to:

- Start date of project
- Work completed till date of report
- Work remaining
- Per patient funds utilized and balance, till date of CRA.

2.3 Bank account shall be opened through "INSTITUTE" accounts department for the research Study. The fund will be transferred to the study account through wire transfer.

2.4 The research grant will only be used for the purpose stated in the grant letter and as per the IEC approved budget.

Section 03: Data sharing

3.1 Either on premature termination / closure or the normal completion of research study, Principal Investigator shall ensure that the data generated by the study will remain with him in a secure confidential manner.

3.2 The complete study data (including but not limited to the raw data) arising out of the study will be used for non-commercial/academic purposes and will remain the property of the PI and Institute. No data will be shared by the PI with the Company from whom the Research Grant and/or free of costs study drugs has been received.

3.3 The Company acknowledges and confirms that no part of this study will be considered for submission to any Regulatory Authority, in the world, to seek marketing authorization for the study drug nor will it use this data for any commercial purposes.

Section 4: Investigational Drug/Device NA ☐

(Please tick NA if no study drugs/devices/others are being provided by Sponsor)

4.1. This study is purely intended for academic research purposes.

4.2 The Investigational drug/device may be supplied by the pharmaceutical/device company/Sponsor; either provided free of cost or cost will be included as part of research

budget.
4.3. The Institution/PI will enroll XX patients from "ÏNSTITUTE" and will acquire the required quantities of the drug only for the purpose of the study and undertake that in no event will sell or distribute the drug in any manner whatsoever, except for the purpose permitted herein.
4.4 Ownership and control of investigational drug:
4.4.1 All Investigational Drug/Device supplied to the Institution shall remain the exclusive property of the Institute and will be administered or dispensed to Subjects by the Institute PI/Study team during the course of the Study.
4.4.2 The Investigational drug/device shall only be used as described in the Protocol and in compliance with Applicable Laws.
4.4.3 Upon termination or completion of the Study, the Institution shall dispose of any quantities of unused Investigational Drug/device, in accordance with Institute policies, after informing the IEC.
4.4.4 The Institution shall maintain complete and accurate records relating to the disposition of the Investigational Drug/device supplied, free of costs, to the Institution.

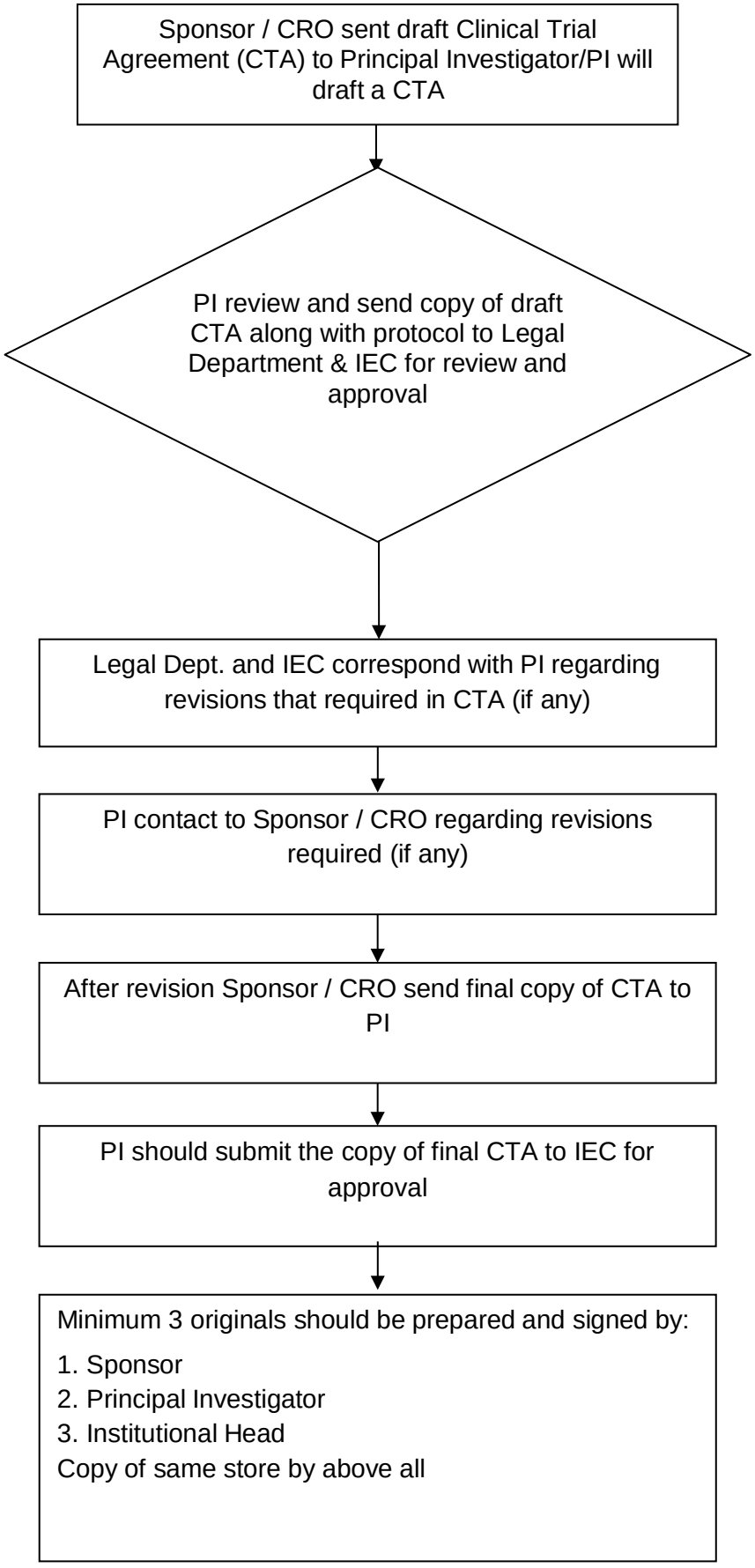
Section 05: Publications

5.1 The results of the study will be submitted by the PI/Institute for the publications in peer reviewed and scientific journals, Posters, Conference presentation.
5.2 The research grant contribution and or study drug/device by the pharmaceutical/device company will be acknowledged.
THIS MEMORANDUM OF UNDERSTANDING IS EXECUTED by the authorized representatives of pharmaceutical and or device company and the Institution as of the date the last signature has been entered.

Other Clauses as required and appropriate shall be added in the final agreement on mutual consent of both the Parties.

PHARMACEUTICAL and or device COMPANY Signature: ..... Name: ..... Title:	[NAME OF INSTITUTION] Signature: ..... Name: ..... Title: .....
PRINCIPAL INVESTIGATOR READ AND ACKNOWLEDGE Signature: ..... Name: ..... Title:	

CTA Process (as modifiable according to institutional policy).



Standard Operating Procedure
Clinical Research Secretariat (CRS)

Title: Study Team Responsibilities

SOP Code: SOP 17/V1.1 Date: 19/Jan/2022 Pages: 134 to 136

17.1 Purpose

To describe the allocation of responsibilities to the study team in order to ensure an appropriate study conduct. .

17.2 Scope

This SOP will apply to all study team members involved in the conduct of study at INSTITUTE.

17.3 Procedure

The Principal Investigator (PI) is the person responsible for the conduct of the research study at site. However, all the other study team members should carry out their roles and responsibilities as assigned by the PI. The investigator should have an adequate number of qualified staff and adequate resources for the duration of the trial. The CV, GCP training certification should be available for all the staff assigned study responsibilities.

Study team involved in a study include, but are not limited to:

- Principal Investigator
- Co-Investigator
- Clinical Trial Coordinator
- Research Nurse/Phlebotomist
- Pharmacists
- Laboratory staff
- Support staff
- Data manager
- Data entry operator

17.4Responsibilities of the Research Team

The delegation of duties and responsibilities by the PI would be documented in form of a Duty delegation and signature log. The template has been added in annexure 1.

The various responsibilities can be listed as follows:

17.5 Applicable Staff

- This SOP applies to the research Team (listed in the Duty Delegation and Signature Log)

AX1-V1.1/SOP 17/V1.1

Duty Delegation and Signature Log

Note this form should only be used for trials where trial-specific forms are not supplied.

Study Title/Acronym:					**Protocol No./ project No:**			
Principal Investigator:					**Study Site:**			
Name	*** Study Role**	****Key Delegated Study Task(s)**	**Initials**	**Signature**	**Start date**	**Signature of PI and date**	**Stop date**	**Signature of PI and date**

List of Responsibilities:

**** Identify key study tasks when delegated by the investigator. Examples of key study tasks include:**

1	Informed Consent process	13	CRF Signature
2	Medical History review	14	IP administration
3	Con. Meds review	15	Data Query resolution
4	Measurement of vital signs	16	Communications with IEC and sponsor
5	Collection of biological samples	17	Study conclusion signature
6	Handling of biological samples	18	Maintaining study records
7	Review of incl./exclusion criteria	19	Randomization
8	Safety assessments, reporting and reconciliation	20	Review & evaluation of reports
9	Authorization to randomize	21	Treatment decision
10	Investigational Product dispensing	22	Archival activities
11	Investigational Product Accountability & maintenance	23	Others
12	CRF Completion and data entry		

Appendix A

List of Abbreviations

Sr. No.	Acronym	Full Title / Description
	AE	Adverse Event
	CA	Confidentiality agreement
	CD	Compact Disc
	CDA	Confidential Disclosure Agreement
	CDSCO	Central Drug Standard Control Organization
	CFR	Code of Federal Regulation
	CIOMS	Council for International Organizations of Medical Sciences
	CIS	Clinical Services- Information System
	Co I	Co-Investigator
	CRC	Clinical Trial Coordinator
	CRF	Case Report Form
	CRM	Clinical Research Methodology
	CRO	Contract Research Organisation
	CRS	Clinical Research Secretariat
	CS	Clinically significant
	CT scan	Computerized Tomography Scan
	CTA	Clinical Trial Agreement
	CRCAE	Common Terminology Criteria for Adverse Events
	CTRI	Clinical Trial Registry India
	CV	Curriculum Vitae
	DCGI	Drugs Controller General of India
	DGFT	Directorate General of Foreign Trade
	DNA	Deoxyribonucleic Acid
	DSMU	Data Safety Monitoring Unit
	EC	Ethics Committee
	ECG	Electrocardiogram
	EDC	Electronic Data Capture
	EMR	Electronic Medical Record
	FDA	Food and Drug Administration
	FDF	Financial Disclosure Form
	GCP	Good Clinical Practices
	GLP	Good Laboratory Practices
	HOD	Head of Department
	IB	Investigator's Brochure
	ICF	Inform Consent Form
	ICH GCP	International Conference on Harmonization Good Clinical Practices
	IEC	Institutional Ethics Committee
	IM	Investigator Meeting
	IND	Investigation New Drug

INR	Indian National Rupees
IP	Investigational Product
ISF	Investigational Site File
IU	Investigator Undertaking
IVRS	Interactive Voice Response System
IW	Impartial Witness
IWRS	Interactive Web Response System
JC	Joint Clinic
LAR	Legally Authorized Representative
MRI	Magnetic Resonance Imaging
MoP	Manual of Procedure
M & V cell	Maintenance & Verification cell
NCS	Non Clinically Significant
NDA	New Drug Application
OPD	Out Patient Department
PET	Positron Emission Tomography
PI	Principal Investigator
PIS	Patient Information Sheet
PSUR	Periodic Safety Update Report
QA	Quality Assurance
SAE	Serious Adverse Event
SDV	Source Data Verification
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
STD	Subscriber Trunk Dialing
Sub I	Sub Investigator
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File

Appendix B
Glossary

Accountability: Refers to the process, documents and records to demonstrate that investigational products(s) have been used in compliance with protocol and an audit trail is available for all the transactions (receipts, dispensing and return) at any given time point.

Addendum: A written formal clarification in an essential trial document (such as protocol, informed consent form, investigator's brochure etc.)

Adverse events (AE): Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Agenda: Refers to a list of topics to be discussed in a meeting.

Agreement: Refers to a document signed between two or more parties describing the terms of agreement.

Amendment: Change(s) made to essential trial documents (such as protocol, ICD, IB, etc) that have an impact on the overall conduct of the study.

Annual Reports: Yearly summary reports submitted to IEC or regulatory agency on the progress of the trial.

Approval Letter: Refer to the action letter from the regulatory agency after the review of a new application, which states that the drug is approved.

Approval: The affirmative decision of the IEC that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IEC, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

Archival: Refer to the storage of data/ records at the end of a clinical trial for the stipulated timeframes.

Archiving: Refers to the place or store (something) in an archive.

Arm: Refer to a treatment group in a randomized trial.

Assent: A process by which a child voluntarily confirms his or her willingness to participate in a clinical trial after having been informed of all the aspects of the trial that is relevant to his/her decision to participate.

Audit: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Auditor: A person appointed by the sponsor who is independent of the study and is qualified by training and experience to conduct an audit of the research study.

Authorized person: A personnel who has the authority to access and review the trial related documents and activities.

Back Translation: Refer to process by which vernacular language translation of a trial documents id back translated into English.

Baseline Assessment: Refer to the pre-treatment evaluations on study participants as they enter a clinical trial and before any investigational products or interventions are given.

Baseline: Refer to the pre-treatment time point of a clinical trial.

Benefit Risk Assessment: Refer to the evaluation of risks that a clinical trial poses to the study participants vis-a-vis-its benefits.

Benefit: Refers to the achievement of a desired outcome in a clinical trial.

Bias: Refers to a systematic tendency built into the design or conduct of the study, which skews the results. Bias can occur systematically across all treatment groups leading to an under or over estimation of the results.

Bill: A printed or written statement of the money owed for goods or services

Biological Sample: A biological specimen including, for example, blood, tissue, urine, etc.

Budget: It is a quantitative expression of a plan for a defined period of time. It may include planned sales volumes and revenues, resource quantities, costs and expenses, assets, liabilities and cash flows.

Budgeting: An estimate of the total cost involved for a particular activity or for the conduct of entire clinical trial.

Calibrated: Mark (a gauge or instrument) with a standard scale of readings.

Calibration: A quantity control process of standardizing the equipments, machine, apparatus etc used in clinical trials.

Carrier: Refers to a person or thing that carries, holds, or conveys something to desired

place/person.

Case Report Form (CRF): A case report form is a paper or electronic questionnaire specifically used in research study. The Case Report Form is the tool used by the sponsor/ Investigator of the research study to collect data from each participating site.

Causality: Determination of the relatedness of an adverse event to the study drug or procedure.

Central Drugs Standard Control Organization (CDSCO): CDSCO is a national regulatory body for Indian pharmaceuticals and medical devices.

Central Laboratory: A laboratory having a centralized function of evaluating the protocol required lab parameters for all the sites involved in a trial.

Centrifuge Machine: Refer to a piece of equipment, generally driven by an electric motor, used to separate the components of blood in blood banks.

Clinical Diagnosis: Refers to both the process of attempting to determine or identify a possible disease or disorder, and to the opinion reached by this process.

Clinical Information System (CIS): It is a part of Hospital Information System. The entries are made at the time of Clinical Assessments and information entered get reflected in the Electronic Medical Record (EMR)

Clinical notes: Records which relate to the physical or mental health of an individual which have been made by or on the advice of a health professional in connection with the care and treatment of that person.

Clinical Research Associate (CRA): A person appointed by the Sponsor or Contract Research Organization (CRO) for monitoring and reporting the progress of the trial and for verification of data. The monitor ensures that the trial is conducted, recorded and reported in accordance with the Protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.

Clinical Significance: Changes in a participants clinical condition considered as important and which may not be related to the study drugs(s).

Clinical Study Report: Written description of the trial enumerating the clinical and statistical interpretation.

Clinical Trial: a systematic study of new drug(s) in human subject(s) to generate data for discovering and / or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug.

Clinical Trail Agreement: A document signed and dated by the investigator, Institution head and the sponsor of a trial that describes the responsibility, timelines, payment schedule and other relevant terms of agreement between the involved parties.

Clinical Research Coordinator (CRC): The Clinical Research Coordinator (CRC) is a specialized research professional working with and under the direction of the clinical Principal Investigator (PI). While the Principal Investigator is primarily responsible for the overall design, conduct, and management of the clinical trial, the CRC supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study. By performing these duties, the CRC works with the PI, department, sponsor, and institution to support and provide guidance on the administration of the compliance, financial, personnel and other related aspects of the clinical study.

Clinical Trial Registry India: It is a free and online system for registration of all clinical trials being conducted in India (www.ctri.nic.in). Registration of clinical trials in the CTRI is now mandatory, as per notification of the Drugs Controller General (India).

Clinical Trial/Study: A systematic study of pharmaceutical products on human participants – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics, pharmacokinetics), and / or adverse effects, with the object of determining their safety and / or efficacy.

Clinical/Contract Research Organization (CRO): An organization to which the sponsor may transfer or delegate some or all of the tasks, duties and / or obligations regarding a Clinical Study. All such contractual transfers of obligations should be defined in writing. A CRO is a scientific body – commercial, academic or other.

Clinical: Related to human participants.

Co Investigator (Co-I): A person legally qualified to be an investigator, to whom the Investigator delegates a part of his responsibilities.

Coercion: Refers to unacceptable subject recruitment procedures, which involves under inducement, duress or indirect pressure to participate in a clinical trial.

Collaborators: Refers to a person who works jointly on an activity or project.

Common Terminology Criteria for Adverse Events (CTCAE) Guideline: Is designed as an instrument to be used to document AEs identified through a combination of clinical and laboratory evaluation. CRCAE is NOT a tool to assist with data extraction from source documents without the direct participation and supervision of clinical investigators.

Common Terminology Criteria for Adverse Events (CTCAE): Common Toxicity Criteria also referred to as the Common Terminology Criteria for Adverse Events, is a standardized classification of side effects used in assessing drugs for cancer therapy.

Communications: Documents narrating the conversation or discussion between two or more patients for e.g. letters, e-mails, fax, telephonic log, etc.

Comparator: A marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

Compensation: Refer to medical care or payment provided to a subject for a trial related injury.

Compliance: Adherence to trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements.

Concomitant Medication: Medication taken by a study subject for diseases/medical conditions other than the study disease.

Confidentiality Disclosure Agreement (CDA): A document used between the Institution and an outside party that defines the terms and basic criteria used to assure that the party (or parties) receiving confidential information (i.e. data, methods, procedures) will maintain the information in confidentiality and will not use the confidential information for any purpose other than that described in the CDA.

Confidentiality: Maintenance of privacy of study participants including their personal identity and all medical information, from individuals other than those prescribed in the Protocol. Confidentiality also covers the prevention of disclosure of sponsor's proprietary information to unauthorized persons.

Congenital anomaly: Refers to a defect that is present at birth.

Consent Form: Documents used to obtain the written, signed and dated consent form a subject for the voluntary participation in a trial.

Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having being informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Contract Research Organization (CRO): An organization to which the sponsor may transfer or delegate some or all of the tasks, duties and / or obligations regarding a Clinical Study. All such contractual transfers of obligations should be defined in writing. A CRO is a scientific body – commercial, academic or other.

Contract: A written, dated and signed agreement between two or more involved parties that sets out arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract. It may also be called as Letter of Agreement (LOA) or Professional Service Agreement (PSA).

Convenience: Refer to the state of being able to proceed with something without difficulty.

Correlation: A measure of the strength of the relationship between two variables e.g. the positive correlation between cigarette smoking's and the incidence of lung cancer; the negative correlation between age and normal visions.

Council of International Organization of medical Sciences (CIOMS): It is an international, nongovernmental, not-for-profit organization established jointly by WHO and UNESCO in 1949. CIOMS serves the scientific interests of the international biomedical community in general and has been active in giving idea of guidelines for the ethical conduct of research, among other activities.

Counseling: The provision of professional assistance and guidance in resolving personal or psychological problems.

CRS Core committee Member: Individual serving as member of Clinical Research Secretariat, INSTITUTE. The Committee has been constituted by Institutional head for CRS support.

Data Archival: The storage of data under proper environmental and access control after the completion of trial.

Data integrity: Refers to maintaining and assuring the accuracy and consistency of data over its entire life-cycle, and is a critical aspect to the design, implementation and usage of any system which stores, processes or retrieves data.

Data queries: A request for clarification on a data item collected for a clinical trial; specifically, a request from a sponsor or sponsor's representative to an investigator to resolve an error or inconsistency discovered during data review.

Data Safety Monitoring Board: A Data Monitoring Committee — sometimes called a Data and Safety Monitoring Board — is an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing.

Data Safety and Monitoring Unit (DSMU): The DSMU is the unit of IEC which is charged with the mission of developing and enacting quality assurance procedures to monitor the overall progress of institutional clinical trials and ensuring adherence to procedural requirements.

Data: Refer to recorded information regardless of form (manual or electronic)

Delegation Log: A document enlisting the roles and responsibilities of each member of the study Team.

Delegation: Allocation of specific trial related duties to the individual study team members in a clinical trial.

Demographic Data: Refer to a Characteristics of participants or study populations, which include such information as age, sex, family history of the disease or condition for which they are being treated, and other characteristics relevant to the study in which they are participating.

Destruction: Clinical trial material (used or unused) destroyed either during or at the end of the trial.

Deviations: A variation from processes or procedures defined in a protocol. Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety, and are often acknowledged and accepted in advance by the sponsor.

Diagnosis: The determination of the nature of disease.

Diary: Forms containing study specific information (safely, efficacy, drug compliance etc.) required to be filled in by the study participants.

Direct Access: An environment in which the access to trial related information is not controlled.

Disability: A substantial disruption of a person's ability to conduct normal life functions.

Disclosure: Refer to release of protected health information of a study subject by one entity to another entity.

Discrepancy: The failure of a data point to pass a validation check

Disease: A condition that impairs the normal functioning of an organism or body.

INTERDISCIPLINARY TEAM members: Individuals serving as a member of the respective Disease Management Group (INTERDISCIPLINARY TEAM). The group has been constituted in accordance with the disease management requirements at INSTITUTE.

Documentation: Refer to records that describes or document study method, conduct and results.

Dose: The amount of drug to be used for a medical condition.

Dosing schedule: Refer to the amount of a drug product to be given at each specific dosing time.

Drop Out: Refer to a study subject who does not complete the protocol specified visits in a clinical trial.

Drug Accountability Log: Logs designed to capture all the transactions (such as receipt, dispensing, return, destruction etc) of an investigational product in order to ascertain 100% accountability at any time point.

Drug Accountability: A process by which accountability of each unit of an investigational product is established.

Drug: As defined by the Food Drug and Cosmetic Act, drugs are articles (other than food) intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human or animal or to affect the structure of any function of the body of human or animals.

Drugs Controller General India (DCGI): The office of Drug Controller General of India under Central Drug Standard Control Organization (CDSCO) having the prime responsibility for regulating clinical trials in India.

Duration: Refers to time scale.

Duty Delegation Log: Am document that enlist the specific trial related duties performed by individual study team members along with their signature, date and/or initials.

e-CRF: Auditable electronic record designed to capture information required by the clinical trial protocol to be reported to the sponsor on each trial subject.

Effective date: The date of approval of the SOPs signed and dated by the RESPONSIBLE PERSON FOR THE INSTITUTIONALCRS and by Director, INSTITUTE, and subsequently the SOP is implemented from that date.

Effective date (CTA): The date of finalization of the CTA signed and dated by the respective persons and subsequently the CTA is implemented from that date

Efficacy: A test products ability to produce beneficial effect on the duration or course of the study.

Eligibility Criteria: Refer to the inclusion/exclusion criteria that make a subject eligible for a clinical trial.

E-mails: Messages distributed by electronic means from one computer user to one or more recipients via a network.

Electronic Medical Record (EMR): It is a digital version of the traditional paper-based medical record for an individual. It is an official health record for an individual that is shared among multiple facilities.

Endpoint: An outcome or event to answer the primary hypothesis of a clinical trial.

Enrollment number: Refers to a unique number allotted to research participants after randomization process.

Enrolment Log: Refer to a log that captures the dates of enrolment and other protocol required information of a clinical trial subject.

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. Essential documents include the Trial Master File, source documents and Case Report Forms (CRFs).

Etiology: Refers to the cause, set of causes, or manner of causation of a disease or condition.

Exclusion criteria: Refer to the criteria that make a subject ineligible for a clinical trial.

Expected event: Refers to the event that has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent.

Facility: Refers to place or site where clinical trials are conducted.

Fax: It is a scanned copy of both text and image printed on a paper, sent from one party to another through a telephone line.

Final Report: Refers to the clinical study report prepared at the end (completion or termination) of a clinical trial.

Financial Disclosure Form: A form signed by Investigators and Sub-Investigators t disclose their financial interest in the sponsor company for whom they intent to participate in the clinical trial.

Follow-up Report: A report/response to provide additional information, clarification, or corrections to a previous report.

Good Clinical Practice (GCP): It is a standard for clinical studies or trials that encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies. It ensures that the studies are implemented and reported in such a manner that there is public assurance that the data are credible, accurate and that the rights, integrity and confidentiality of the participants are protected. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the "Investigational Product" are properly documented.

Good Laboratory Practices (GLP): A standard for the conduct and reporting of non-clinical laboratory studies intended to assure the quality and integrity of safety data submitted to regulatory authorities.

Grants: Refer to the financial assistance provided by the funding agency/sponsors to carry out a research projects.

Guidelines: Refers to a document that aims to streamline process according to a set routine.

Handover: an act or instance of handing something over to another delegated person.

Hospitalization: Refer to a condition that requires admission to a hospital for its management.

IEC members: Individuals serving as regular members of the Institutional Ethics Committee, INSTITUTE. The Committee has been constituted in accordance with the EC membership requirements set forth in Schedule Y

IEC membership roster: A form in which names of IEC members are enlisted.

Illiterate participants: Participant who is unable to read and write in any language, but can, speak, understand and is conscious enough to make informed voluntary decision.

Impartial Witness (IW): Impartial Witness is a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject."

Inclusion and Exclusion Criteria: The characteristic that must be present (inclusion) or absent (exclusion) in order for a subject to qualify for a clinical trials, as per the protocol for the trial.

Inclusion Criteria: Specifications of the participants (patients / healthy volunteers) including age, gender, ethnic groups, prognostic factors, diagnostic admission criteria etc. for

participation in a research study.

Inconveniences: The state or fact of being troublesome or difficult with regard to one's personal requirements or comfort.

Investigational New Drug (IND): Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

Indemnification: A legal statement or document indicating protection or exemption from liability for compensation or damages from a third party.

Informed Consent Form (ICF): A document that describes the rights of the study participants and includes details about the study such as its purpose, education, required procedures, risk, potential benefits and key contacts.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of trial that are relevant to the subject's decision to participate. Informed Consent is documented by means of a written, signed and dated informed document (ICD)

Injury: An instance of being injured

Institution: Any public or private medical facility where a clinical study is conducted.

Institutional Ethics Committee (IEC): It is an independent body formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the participants. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial and to provide public assurance of that protection.

Integrity: The quality of being honest and having strong moral principles.

Interactive Voice Response System (IVRS): IVRS is a System or a phone technology that allows a computer to automatically detect voice and touch tones using a normal voice phone. It helps in clinical trial and Pharmaceutical industry for efficient Clinical trials data management, error-free study of clinical trials, reduction of monotony and cumbersome work, thereby meeting the challenges and requirements of rapidly growing Clinical research and pharmaceutical industry.

Interactive Web Response System (IWRS): Interactive Web Response System is service to facilitate the logistical issues surrounding the conduct of clinical trials. This system works using a standard web browser and email service, allows study administrators and investigators to security interact with the study database, making study development fast and easy.

International Conference on Harmonization-Good Clinical Practice (ICH-GCP): Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human participants. Compliance with this standard provides public assurance that the rights, safety, and wellbeing

of trial participants are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Investigational Product (IP): A pharmaceutical product (including the Comparator Product) being tested or used as reference in a clinical study. An Investigational Product may be an active chemical entity or a formulated dosage form.

Investigator Meeting (IM): A meeting conducted before initiating a clinical trial for the uniform understanding of the protocol, processes and trial logistics among all the participating trial sites.

Investigator Statement: Refers to agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Investigator Training: Refers to imparting training on study protocol, trial procedures and processes to the investigator.

Investigator Undertaking (IU): A formal written, commitment (submitted to regulatory authorities) by trial investigator(s) assuring their compliance with the study protocol and all the applicable regulatory requirements.

Investigator: A person responsible for the conduct of the study at the trial site. Investigator is responsible for the rights, health and welfare of the study participants. In case the study is conducted by a team of investigators at the study site then the designated leader of the team should be the Principal Investigator. Also see Principal Investigator, Sub-investigator.

Investigator initiated studies: Academic institutions routinely carry out investigator initiated clinical trials. In such trials, the investigator has the dual responsibility of being an investigator as well as the sponsor.

Investigator's Brochures (IB): A compilation of the clinical and nonclinical data on the investigational drug(s) that is relevant to the study of the investigational drug(s) in human participants.
IP number: Refers to the unique number given on the investigational product.

Laboratory Normal Ranges: Refer to the normal value ranges for standardized laboratory tests.

Laboratory Report: Refer to a document that contains results of the laboratory test for a specific subject.

Legal Expert: A legal scholar versed in civil law or the law of nations to protect the peoples involved in the clinical research

Legally Acceptable Representative (LAR): A LAR is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure as per research protocol.

Less than minimal risk: Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.

Lost to follow up: Refer to a trial subject who is not traceable by any means before completion of his/her participation in the trial.

Lot/batch number: Refers to a unique number provided on the investigational product for identification.

Literate Participant: A participant who can read, write, understand and speak any language.

Maintenance: The process of preserving a condition or situation or the state of being preserved.

Material Transfer Agreement (MTA): A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use them for their own research purposes.

Master SOP files: An official collection of the Standard Operating Procedures (SOP) of CRS, INSTITUTE accessible to all staff, Investigators, Researchers, auditors and government inspectors as a paper copy with approval signatures

Medical History: The information on overall general health, past illnesses and current medical problems of a subject.

Medical record: The case history of a medical patient as recalled by the patient. Original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, participants diaries or evaluation checklist, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified aft6er verification as being accurate and complete, microfiches, photographic negatives, microfilms or magnetic media, X-rays, participants files, and record kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Minimal risk: Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor Protocol deviation: Changes or alterations in the conduct of the trial which do not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

Minor: An individual who has not attained the legal age of consenting to a trial as per the applicable regulations.

Modification: The act of making changes or amendment to an information, document or

process.

Memorandum of Understanding (MoU): A document intended to describe a bilateral or multilateral agreement between parties. It is often a preliminary document and is generally not intended to create a legal commitment between the parties but to set out the working principles of the relationship.

Monitor: A person appointed by the Sponsor or Contract Research Organisation (CRO) for monitoring and reporting the progress of the trial and for verification of data. The monitor ensures that the trial is conducted, recorded and reported in accordance with the Protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.

Monitoring Visit report: A written report prepared by the monitor after each site visit to document the progress and conduct of clinical trial at site.

Monitoring: The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Non-compliance: Non-performance of the study in compliance with the approved protocol, national regulations, ICH GCP, and other applicable regulations and/or failure to respond to the IEC request for information/action.

Non-expected event: Refers to the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochures for an unapproved investigational product or package insert/summary of product characteristics for an approved product).

Non-Investigator Initiated Studies: Studies not initiated by Investigator and supported by sponsor or initiated by the Sponsor or collaborators.

Normal value ranges: Refers to the normal value ranges for standardized laboratory tests of any laboratory.

Notes to File: Refers to the notes to explain the deviation/violation of a particular activity/process.

Offsite: Event occurring at other centers/sites

Onsite: Event occurring at site

Out patients Department (OPD): OPD is a department in which patient are seen on daily basis.

Outdated version: When revised version of protocol/ICF/IB etc. published, the old version is no longer effective and it is called as outdated version.

Pamphlet: Refer to a small booklet or leaflet containing information or arguments about a

single subject.

Participants: Refer to a subject who takes part in a clinical trial.

Patient Case Files: Refer to the hospital/clinic file that contains complete medical information of a patient/subject.

Patient Diaries: Refer to a document given to the participants for recording certain observations/readings on the condition of their health either at home or at trial site.

Patient ID :A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

Patient: Refer to an individual who required medical care or treatment.

Payment: The action or process of paying someone or something or of being paid.

Pharmacist: Refer to a person qualified to prepare and dispense drugs and certified by concerned authority to do so.

Pharmacy: Refer to a place where drugs are prepared and dispensed.

Photocopies: Refers to a photographic copy of printed or written material produced by a process involving the action of light on a specially prepared surface.

Premature Termination: Early termination of a trial before data is sufficiently strong to be convincing.

Previous SOPs of the CRS: A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations

Principal Investigator (PI): The investigator who has the responsibility to co-ordinate between the different Investigators involved in a study at one site or different sites in case of a multi-center study.
Privacy: Refer to a state of being private.

Procedure: A particular method of performing a task.

Protocol Amendments: Any changes or formal clarifications appended to the protocol.

Protocol compliance: Adherence to trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements given in protocol.

Protocol deviation: Changes or alterations in the conduct of the trial which do not have a major impact on the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

Protocol Feasibility: An analysis of the ability to complete a project successfully, taking into account legal, economic, technological, scheduling and other factors. Rather than just diving

into a project and hoping for the best, a feasibility study allows project managers to investigate the possible negative and positive outcomes of a project before investing too much time and money.

Protocol violation: A protocol deviation that may affect the participant's rights, safety, or well being or alter the risk benefit ratio, and/or affect the participants' willingness to participate in the study, and/or impact the completeness, accuracy and reliability of the study data.

Protocol Waiver: Protocol Waiver is analogous to a Protocol Deviation, except that prior IEC approval must be obtained before implementing the necessary departures from the protocol.

Protocol: A document that states the background, objectives, rationale, design, methodology (including the methods for dealing with AEs, withdrawals etc.) and statistical considerations of the study. It also states the conditions under which the study shall be performed and managed.

Publication: Refer to publishing the results of a clinical trial in a peer-reviewed journal.

Quality: Refer to pre set standard for measuring the outcome.

Queries: A request for clarification on a data item collected for a clinical trial; specifically, a request from a sponsor or sponsor's representative to an investigator to resolve an error or inconsistency discovered during data review.

Random: Refer to an element of chance or having no specific pattern.

Randomization: Refer to the process of assigning trial participants to treatment or control groups using an element of chance in order to reduce bias.

Recipients: Individual who would receive a copy of SOP

Re-consenting: Refer to a process of again consenting a subject in the same protocol.

Recruitment: Refer to the act of enrolling participants with the proper inclusion criteria.
References: Refer to a list relevant published literature on a topic along with complete citation.

Reimbursement: Is an act of compensating someone for an expense often; a person is reimbursed for out-of-pocket expenses when the person incurs those expenses through employment or in an account of carrying out the duties for another party or member

Related Event: Refer to an adverse event that is related to the administration of investigational products.

Relatedness: Refer to the extent of relationship between occurrence of an adverse event and administration of investigational of a drug/ placebo.

Requestors: Investigators, Sponsors, Contract Research Organizations, Regulatory authorities, Hospital administrators, and such others.

Requisition forms: An official form on which a request in made.

Research Nurse: Refer to the qualified nurse who assists the investigator in the conduct of a research project.

Research Team: Investigator, Co Investigator, Clinical Trail coordinator and research nurse involved with the study.

Revision date: Date/year by which the SOP may be revised or reviewed.

Rights: that which is morally correct, just, or honorable.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Safety assessment: Refer to the assessment of adverse event and serious adverse events experienced by the participants in a clinical trial.

Safety Recording: Refer to the process of proper recording of the safety events information arising in clinical trials after administration of IP.

Safety: Refer to the condition of being protected from or unlikely to cause danger, risk, or injury.

Schedule Y: Requirements and guidelines on clinical trials for import and manufacture of new drug

Scheduled visit: A clinical encounter that encompasses planned trial interventions, procedures, and assessments that may be performed on a subject.

Screening and/or enrollment logs: The form includes a log of participants who were screened, screen failures, enrolled, withdrawn, and completed the study.

Screening Log: Refer to a log captures the details of all the participants screened for a clinical trial.

Screening number: A number is given when a potential subject for enrollment in a trial is entered in screening log.

Screening Reports: Various reports which are being perform to check that the patient is eligible for enrolment in the trial or not.

Serious Adverse Event (SAE) : Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapability.

Shipment: Refers to the action of shipping goods.

Site Activation: After site selection, it takes several steps to bring a site to the point where it is ready to recruit patients. This process is called site activation, and it consists of a variety of tasks including: Negotiate a financial contract, Gain approval from Institutional Review Board (IRB) or, EC, Provide clinical supplies, obtain other documents from site (CV, financial disclosure, etc

Site Closeout: Refer to closing a clinical study after the same has been completed or prematurely terminated/suspended.

Site Initiation: Refers to the activation of a site for initiation a clinical trial after the ethics committee and regulatory approval has been obtained and other trial specific requirements have been fulfilled.

SOP Team: A team of members selected from the CRS including the CRS Core Committee, TRAC members and Clinical Trail Coordinators as identified by the RESPONSIBLE PERSON FOR THE INSTITUTIONALCRS who oversee the creation, preparation, review and periodic revision of the CRS, INSTITUTE SOPs

Source data verification: Refer to the verification of source documents and other trial records for accuracy, completion and compliance with protocol, GCP and applicable regulatory guidelines.

Source documents: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Sponsor: An individual or a company or an institution that takes the responsibility for initiation management and/or financing of clinical study. An Investigator who independently initiates and takes full responsibility for trial automatically assumes the role of sponsor. Here sponsor refers to individuals or organization that pays for or contributes to the costs involved in conducting clinical trials. e.g: Pharma companies, collaborators, Device Company, biological material.

Sponsor-Investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

Standard Operating Procedures (SOP): Standard elaborate written instructions to achieve uniformity of performance in the management of clinical studies. SOPs provide a general framework for the efficient implementation and performance of all the functions and activities related to a particular study.

Study Subject (Subject): An individual participating in a clinical trial as a recipient of the Investigational Product. A Study Subject may be a healthy person volunteering in a trial or a person with a medical condition that is unrelated to the use of the Investigational Product or a person whose medical condition is relevant to the use of the Investigational Product.

Study Team: Refer to a group of individual including investigators, research fellows, resident, research nurses etc. to perform clinical trial-related procedures and/or to make important trial-related decisions.

Study Termination: The clinical study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated.

Suspected Unexpected Serious Adverse Reaction (SUSAR): An adverse reaction that is both unexpected (not consistent with the applicable product information) and also meets the definition of a Serious Adverse Event/Reaction.

Suspension: The clinical study has stopped recruiting or enrolling participants early, but it may start again.

Temperature Log: A log that captures the storage temperature (minimum/maximum) of investigational products on a daily basis.

Termination: The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject.

Toxicity: An adverse effect produced by a drug that is detrimental to the participant's health.

Training Log: A documented trail of all the trainings undertaken by clinical research personnel. It generally includes the topic of the training, training modality, completion date and signature of the personnel.

Transfers of Patients: Refer to the process of transfer of participants to another place/hospital for investigation/any other study related procedure.

Trial Master File (TMF): A trial master file contains essential documents for a clinical trial that may be subject to regulatory agency oversight. The trial master file should consist 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 and guidelines of good clinical practice and with the applicable requirements. The Trial Master file should be created and maintained in accordance with ICH-GCP guidelines.

Unanticipated issues: Issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review.

Vendor: Refer to a supplier of goods or services.

Version: Refer to the number assigned to an essential document in use. Version number is important to provide an audit trial.

Voluntary: The act of giving one's own free will without any coercion or undue inducement.

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