



Somani Hospital & Research Center

PURPOSE

To describe the procedures to conduct and manage clinical studies in accordance with site standards, study specific protocol and applicable regulatory requirements.

DESCRIPTION OF PROCEDURES

General

1. The principal investigator (PI) is overall responsible for the conduct and management of the clinical trial at the site. The PI can delegate duties to trained and qualified individuals at the site but the overall responsibility of the trial lies with the PI.

Ethics Committee

1. The PI should approach Institutional/Independent EC for the permission to conduct a clinical study in the hospital/institution.
2. The PI should submit all the study documents in the prescribed format as per the EC SOPs.
3. Ongoing communication and correspondence with the EC should be done by the PI primarily. In case the PI is not available at the hospital/institute then a PI delegated personnel should be sending the communication on behalf of the PI.
4. The trial should be initiated by the sponsor at the hospital/institute after receiving appropriate approvals from the EC and DCGI

Informed Consent Process

1. The PI or delegate can start recruiting subjects for any clinical study after obtaining approvals for the study from EC & DCGI and the sponsor/CRO representative initiates the site.
2. The prospective subject would register himself / herself at the registration counter / reception at the site and would be provided a unique hospital record number.
3. If prospective subject is deemed suitable for the trial then the Investigator and/or delegate has to dedicate time for the discussions on the informed consent process with the prospective subject. If the subject is willing to take the ICF document home and then come to a consensus to participate in the study then a copy of the ICF should be handed over to the subject.
4. Discuss all the points mentioned in the ICF. After complete discussion on the ICF and if the subject is willing to participate then the subject should be requested to sign and date the ICF

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5. Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the patient as provided by the law(s) of India). If the Subject or his/her legally acceptable representative is unable to read/write – an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.
6. A copy of the signed ICF should be provided to the subject/LAR
7. The discussions of the ICF should be documented in the source file/hospital file of the individual subject and a study screening number should be assigned to the subject.
8. Perform the screening assessments as per protocol and document the observations in the source/hospital file of the individual subject.
9. If required as per the protocol, the prospective subject should be accompanied to other departments where specific study assessments would be performed.
10. If applicable, the other departments should be notified well in advance about the study specific requirements.

Source Documents

1. The subject's source documents will be maintained in the clinical research room/MRD/Document room during the study.
2. For IPD based studies, the patient charts and any other form of documents should be reviewed in a timely manner by the PI or delegated medical personnel. These documents would be included in the source file/ hospital file of the subject.
3. All the source documents should be original / certified copies, legible and accurate. Any errors in the source documents should be stroked off with a single line and correct entry should be made so that the erroneous entry is also visible. The corrections in the source documents should be initialed and dated by the individual who is involved in making the correction and the PI or delegated qualified personnel if required.
4. All observations or communications that occur between the subject and the site staff must be documented in the source file on real time basis. In case real time entry not done then reason for the same should be documented in the source documents.
5. The PI is responsible for writing the source documents. This activity can be delegated to qualified personnel as per the duty delegation log.

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Investigational Product/study drug

1. After the receipt of the IP/ study drug at the site, the transit temperature should be checked whether in compliance with the protocol. In case there is temperature excursion, this should be notified to the sponsor representative immediately in writing. Similarly if the IP/study drug is not received in good condition or any other discrepancy then the same should be notified to the sponsor representative immediately in writing.
2. IP / Study drug acknowledgement receipt should be signed & dated. The same should be filed in the site file and a copy should be sent to the sponsor.
3. The IP/study drug after the receipt at the site should be stored as per the protocol requirements and sponsor specific temperature logs should be updated on an ongoing basis. In case there is a temperature excursion during the storage of the IP, then the sponsor representative should be immediately notified in writing and wait for further course of action.
4. The IP accountability logs in terms of IP quantities received, dispensed, administered, returned by subject and returned to sponsor/destroyed should be maintained in the site file by the PI delegated staff.
5. The IP should be stored in the designated area and should have restricted access.
6. IP administration/dispensing should be done by PI or delegated qualified staff to the study specific subjects who are eligible to receive the IP as per the inclusion & exclusion criteria of the protocol. The entries in the log should be completed by PI delegated personnel.
7. The process of IP administration to the subjects should be done in accordance with the study specific protocol requirements.
8. The IP cannot be distributed to any person who is not authorized to receive it.
9. For blinded studies, the codes should be appropriately maintained throughout the study. The blinded codes should be broken in accordance to the protocol only and should be recorded and reported as per the protocol requirements.

Case Report Form/CRF

1. The entries in the CRF should be made by PI delegated staff.
2. All the entries in the CRF should be made from the source documents.
3. Study specific CRF filling instructions should be followed for completing the CRFs.

Adverse Event /Serious Adverse Event Reporting

1. All AEs and SAEs should be reported as per GCP and applicable regulatory requirements.

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2. AEs should be documented in the source and the CRF.
3. All SAEs should be documented in the source & CRF, notify the sponsor within 24hrs of the knowledge of the event and within 7 working days to the EC.
4. The SAE form should be completed by PI or qualified personnel delegated by the PI as per the duty delegation log. All the supporting documents if required like lab reports, source documents, details of hospitalization, ECG reports etc should be attached to the SAE form.
5. Ensure to mask the subjects name and enter the study specific number on all the documents that are been sent to the sponsor as supporting to the SAE form.
6. Follow up with the subjects on an ongoing basis until and unless the AE/SAE is resolved.
7. Document all the medications, treatments or procedures that have been performed on the subject during the AE/SAE.
8. In case the PI is not available at the site during the reporting of the SAE by the subject then PI delegated qualified personnel would be responsible to inform the PI regarding the SAE and take medical care of the trial subject.

Investigator Site File

1. The ISF should be maintained as per the table of contents provided by the sponsor and ICH GCP guidelines.
2. The ISF should be updated on an ongoing basis by the PI or PI delegated personnel as per the delegation list.
3. The ISF should be reviewed on an ongoing basis for completeness by the delegated personnel.
4. All the documents related to the study should be filed in the respective section of the site file.

Protocol Compliance

1. The PI should ensure that the trial staff is performing all the activities in compliance to the specific protocol, GCP and applicable regulatory requirements.
2. Any deviations to the protocol, GCP and applicable regulatory requirements should be intimated in a timely manner to the sponsor & EC with reasons for deviation, corrective and preventative action.

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3. Deviations that are noted by the sponsor representative during the monitoring visit should be notified to the EC within a stipulated timelines and it should be ensured that the same are not repeated during the future course of the trial.

Monitoring

1. The PI should be available to discuss the monitoring observations with the sponsor representative.
2. The PI should ensure that the delegated personnel should be present and provide all the study related documents to the sponsor representative to carry out monitoring activities.
3. The PI should ensure that all the action items should be completed within a stipulated period of time by the delegated personnel.

Study Closure

1. The PI should receive in writing from the sponsor regarding the closure of the study and notify the EC in a timely manner.
2. The PI or qualified delegated personnel should ensure that Source documents, lab kits, IP and any other study specific materials should be treated as per the requirements of the protocol, GCP and applicable regulatory requirement..
3. All source documents should be archived as per the study requirements.

Audits/Inspections

1. The PI should inform the hospital/institutional authorities regarding any audits/inspections planned for the study.
2. In case of inspection, the PI should ensure to inform the sponsor immediately regarding the inspection after the knowledge of the same.
3. All the study specific source documents, IP (if available) and study files should be made available to the auditor / inspector upon request. No document should be provided to the visitor if the same is not requested.
4. Observations of the Audit/Inspection should be responded within stipulated time period. In case of any actions items proposed by the visitor, the same should be discussed and if possible implemented for all the clinical trials.

References

ICH E6 Good Clinical Practice
Schedule Y
Indian GCP Guidelines

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