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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Study Team Responsibilities SOP** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose**

To describe the division and allocation of responsibilities and to clarify boundaries of responsibility within the study team, to ensure smooth running of the study under applicable regulatory requirements.

1. **Scope**

This SOP applies to [*all study team members*] involved in study activities conducted by [*research group*].

1. **Responsibilities**

All members of the [*research group*] have a responsibility to work within the relevant SOPs for their role and for bringing any deficiencies in the SOPs that they notice to the attention of the [*research group management*].

1. **Associated templates/forms**

Individual Responsibilities sign off sheet

Site Delegation of Duties Log

1. **Glossary/definitions**

[Add as appropriate] *[Consumer group]*

1. **Procedure *[Responsibilities of individuals research team members]***

**Principal** **Investigator** **(PI)** **/Co** **Principal** **Investigator** **(Co** **PI)**

* 1. Each research study will have a Principal Investigator (PI) *[and may have a Co PI]* who is the individual of a record who assumes authority and accountability for the ethical conduct of a research study in accordance with all applicable federal and state laws and state laws and regulations and with institutional policy. The PI *[and Co PI]* is each fully responsible for:
     1. The Investigator(s) shall be responsible for the conduct of the study according to the protocol; the relevant local and international guidelines good clinical practice guidelines (GCP) and for compliance purposes as per the undertaking given in Appendix *[labelled according to group standardized nomenclature]*
     2. The safety and welfare of participants in the *[research study/trial]*
     3. Reading and understanding all the information in the essential documents, the investigator’s brochure (IB), the informed consent, and the protocol.
     4. Informing all participants, including participants used as controls, that the investigational agents are being used for investigational purposes and following all requirements relating to obtaining informed consent.
     5. Preparing and submitting protocol documents for initial IEC review and approval. Conducting study activities only after IEC approval and in accordance with the approved protocol, and assuring that IEC requirements are met.
     6. Reporting Adverse Events (AEs) to the Sponsor as per protocol.
     7. Implementing modifications in approved research only after review and approval of the modification by the IEC, except where necessary to eliminate apparent immediate hazards to participants.
     8. Appropriate control, inventory, distribution, storage, record keeping and destruction or return of Investigational Product (IP).
     9. Prompt reporting to the IEC of all events that require prompt reporting. o Providing progress reports/annual report to the IEC in a timely manner.
     10. Assuring the disclosure of financial interest and arrangements to the sponsor and the IEC, and if required by the IEC, to participants, by any member of the research team that may present a conflict with the interests of participants in the study.
     11. While retaining knowledge of and overall authority for the conduct of all research studies, supervise members of the research team qualified by appropriate education and experience to accept responsibility for study-related activities not directly performed by the PI. Assuring that delegation of responsibilities is appropriate and is documented (AX1-V3/SOP 05/V3) and that individuals recruited as members of the research team are appropriately licensed and trained.
     12. Maintaining adequate and accurate records and making records available for inspection to external and internal monitors. Meeting with auditors (DCGI, FDA, sponsor and internal), at the conclusion of their audits, to review findings and to implement changes to correct weaknesses or deficiencies
     13. The PI/Co PI may delegate responsibility to individual members of the research team; however, the PI/Co PI cannot delegate accountability for the ethical conduct of the study. The PI must sign the form that he/she delegates the responsibilities to each member of the research team. Each individual’s name must be signed initialed and dated. The form must be updated, signed initialed and dated, each time there is a personnel change (AX1-V3/SOP 05/V3)

**Responsibilities of Sub-Investigator (Sub I) /Co-Investigator (Co I)**

* 1. A Sub Investigator (Sub I) or Co-Investigator (Co I) is a member of the study team who is qualified by education, experience, and with appropriate licensure or certification, designated responsibilities by the PI at a *[trial/study]* at a trial site to perform critical trial-related procedures or to make important trial-related decisions.
     1. The Principal Investigator can assign some or all of his/her study related duties at the study site(s) to his subordinate who is under the supervision of the principle investigator.
     2. Sometimes the responsibilities designated by the PI could be the same as PI responsibilities. (Refer PI responsibilities).

**Research Manager- Clinical Research**

* 1. The post holder will have the lead role in planning, co-ordinating and completing the project. They will have excellent communication and presentation skills, together with the ability to organise and motivate others. They will demonstrate flair, enthusiasm, innovation and leadership when faced with challenges and will provide strategic, tactical and operational management and coordination of clinical trials is desirable but not essential; however, appropriate academic and/or vocational qualifications are necessary. The researcher manager is responsible for:
     1. Overall efficient day-to-day management of all the trials
     2. Recruitment, retention, training, appraisal and supervision of *[trial/study]* team members.
     3. Establishment of procedures to ensure adherence to trial protocols, regulatory and administrative requirements.
     4. Ensuring the timely recruitment of trial participants with secure randomisation processes *[when required]* and subsequent efficient and effective data management *[if and when required]*
     5. Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems
     6. Management of the trial budget (s) and maintenance of the accounts.
     7. Act as the point of contact for all external and internal agencies.
     8. Co-ordinate the preparation and publication of data, reports and information, ensuring that these meet legislative, contractual and ethical requirements.
     9. Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and co-ordinating any necessary audit processes.
     10. Liaison with the Trials Steering Committee *[if and when required]* and Data Monitoring and Ethics Committee/Data Safety Monitoring Board *[if and when required]* with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements.
     11. Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsors, to include reports, updates, guidance, commitments and, possibly, a newsletter.
     12. Work with chief/lead investigator to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding or time.
     13. Ensure the inclusion of consumer group representatives at the appropriate levels and times.
     14. Planning and supporting the meetings and work of the various groups and bodies associated with the *[trial/study].*
     15. Creation and maintenance of all trial files, including the trial master file, and oversight of site files.

**Asst Manager-Clinical Research Responsibilities**

* 1. It should be documented in each clinical trial's Investigator Site File (ISF) which SOPs are being used. Templates/forms may be updated independently of the SOP to which they are referenced as long as they are version-controlled and remain compliant with GCP and institutional/regulatory/ethical requirements.
  2. SOP review:
     1. SOPs should be reviewed before any new clinical trial and every [*second*] year if trials are active during that period; however deficiencies in existing SOPs noted at any time (by any member of the [*research group*]) which require action are raised and dealt with at the earliest opportunity.
     2. New SOPs may also be suggested via email by any member of the [*research group*] for consideration by the [*research group management*]. The latter will facilitate a meeting of relevant key members of the [*research group*] to decide whether the new SOP is required and, if so, an outline for its contents and assignment of author/reviewer.
     3. In case of revisions, a summary of any changes are kept in the document history section. The revised SOP will be assigned a new version number/date according to a standard format.

1. **References**

* 21 CFR 312.60 – General Responsibilities of Investigators
* Guideline Good Clinical Practice
* ICH Guidelines for Good Clinical Practice (E6)
* ICH Guidelines for Good Clinical Practice (E6) section 3.1 – Responsibilities
* Schedule Y : Responsibility of Investigator

1. **Document history**

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| --- | --- | --- | --- |
| **Version no.** | **Date** | **Reviewer** | **Details of changes** |
| 1 |  |  | Not applicable, first version |
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