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

**9.1 Purpose**

This SOP describes the procedures study team will use for recruiting eligible subjects into a study while following protocol and fulfilling ethical responsibilities for protecting the rights, safety and welfare of participants and maintenance of a screening log.

**9.2 Scope**

This SOP will apply to all clinical studies being conducted at [INSTITUTION].

**9.3 Procedure**

There are several steps involved in subject recruitment. These can be summarized into developing a recruitment plan or strategies and activities covering the entire recruitment period, including pre-screening and screening the subject to ensure that they meet the inclusion and exclusion criteria; and the enrolment in the study.

ICH GCP requires that records are kept of every subject that undergoes pre-trial screening (ICH GCP 8.3.20) i.e. details of all subjects approached for a study should be maintained. For the purposes of this SOP, this shall be referred to as a screening log.

**9.3.1 Recruitment strategies**

The Investigator must schedule a meeting prior to enrolment, in order to secure the co-operation of study team to obtain a sufficient number of subjects.

During the meeting the study protocol will be revised/ re discussed and the inclusion and exclusion criteria will be discussed in detail.

The Investigator will provide the detailed inclusion and exclusion pamphlet to the entire study team member to place in their respective OPDs.

Using the eligibility criteria for the study, the Investigator/study team or CTC will review records from the Investigator’s subject population to determine the suitability and availability of candidates for the protocol.

The Study team should inform the Investigator/ CTC, if they identify any potential subject for the study.

Any queries regarding subject eligibility must be referred to the Principal Investigator.

The investigator is responsible for ensuring the unbiased selection of an adequate number of suitable subjects according to the protocol.

The CTC must review the screening check list to ensure that all the protocol specific screening procedures are performed.

The Investigator and CTC will review the screening reports and will confirm subject eligibility.

If investigator finds the prospective subject eligible, investigator must inform the same to the subject and the sponsor/CRO.

If a prospective study participant found to be ineligible, inform the same to subject and or LAR and document the reasons for screening failures in the enrolment log and in the source documents. Store the enrolment log in the study files.

**9.3.4 Subject randomization/enrolment**

Enroll eligible participants into the study and follow the trial's randomization procedures, if any.

When a subject is enrolled in a study, the following information will be entered on the source notes:

* Subject randomization number/enrollment number
* Date of randomization/enrollment
* Randomization group/arm
* Document recruitment activities on the source notes and/or enrollment log as appropriate while maintaining subject/participant confidentiality.

If the trial is blinded, the investigator should promptly document and explain to the sponsor in case of premature unbinding (e.g., accidental unbinding, unbinding due to a serious adverse event) of the investigational product(s) and should ensure that the code is broken only in accordance with the protocol.

**9.4 Applicable staff**

This SOP applies to all the personals of the clinical research team and others who may be responsible for subject recruitment in the study. These include the following:

* Investigator
* Research Team (listed in the delegation log)
* CTC

**9.5 Staff responsible for Implementation**

The research department and Investigator will ensure that the research team involved in the conduct of the study will comply with this site SOP.

The PI will ensure that at the time of implementation of the SOP, that the research team at the clinical research unit in [Institution] are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.

**References**

1. 21 CFR 312.60 – General Responsibilities of Investigators

2. 21 CFR 50.20 – General Requirements for Informed Consent

3. 21 CFR 50.25 – Elements of Informed Consent

4. Guideline Good Clinical Practice

5. ICH Guidelines for Good Clinical Practice (E6)

6. ICH Guidelines for Good Clinical Practice (E6) section 3.1 – Responsibilities

7. Schedule Y