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

1. **Purpose**

SOPs are documents containing detailed, unambiguous written instructions for a research team relating to common or important tasks/practices. This SOP describes the procedure for preparation, review, authorisation, distribution and control of SOPs for the [*research group*].

1. **Scope**

This SOP applies to [*all clinical trials of investigational medicinal products*] conducted by [*research group*].

1. **Responsibilities**

The [*research group director/PI*] will assign responsibility for authorship, review and authorisation to suitably qualified and experienced members of the [*research group*]. All members of the [*research group*] have responsibility for working within the relevant SOPs for their role and for bring any deficiencies in the SOPs that they notice to the attention of the [*research group management*].

1. **Associated templates/forms**

SOP log

1. **Glossary/definitions**

[Add as appropriate]

1. **Procedure**
   1. The [*research group management*] will delegate preparation (authorship and review) of SOPs to appropriately qualified and experienced personnel.SOPs should be clearly labelled as draft during the development process, prior to being authorised.
   2. The author develops a draft/amended SOP using a consistent format of this SOP, ensuring it is passed onto the assigned reviewer/review group within agreed timelines.
      1. Sections should cover relevant background and the reason an SOP exists (purpose), areas of work/staff the SOP applies to (scope), who is involved in which tasks (responsibility), and details of the tasks to be conducted under the SOP, including when they are to be accomplished, where, and by whom (procedure). In addition SOPs may contain references and/or associated templates/tools/forms etc. These must be clearly labelled in relation to the parent SOP.
      2. SOPs should be consistent with the applicable authorities’ requirements (e.g. ICH GCP, [*regulatory authority*] and [*ethics committee*]) and be practical/fit for purpose for use within a broad range of clinical trials.
      3. Processes that are mandatory are described using ’should’, ‘must’ etc., while processes that are recommended are described using ‘may’, ‘could’ etc.
      4. Abbreviations/acronyms should be explained in full the first time they are used and/or a glossary included. The glossary should be based on accepted definitions according to national and international GCP or other relevant documents.
      5. At the time of authorisation an effective date for implementation will be assigned.
   3. Storage and distribution
      1. Paper master SOPs of current and superseded SOPs are maintained in a file in a secure location by [*staff role*], with an electronic current copy in pdf format available to all trial staff through a shared directory.Electronic copies will also be archived once approved.
      2. A log is kept by the [*staff member*] of current and superseded SOPs (SOP log).
      3. Working copies of SOPs may also be placed in convenient locations (e.g. trial sites, research wards) during a trial. All users should ensure that any printed SOP they are working from is the current version on the electronic directory.
      4. Notification of a new SOP will be sent to relevant members of the [*research team*] with an instruction to staff as to how to return/effectively destroy any superseded versions.
      5. The [*staff member*] then facilitates training in SOPs for staff. Training is detailed in a training attendance record filed in each team member’s training record (see [SOP] for training).
   4. 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.
   5. 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.
2. **References**
3. **Document history**

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