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

1. **Purpose/scope**

To describe the procedure for receiving Investigational Medicinal Product (IMP) for a clinical trial conducted by the [institution/group], including placing it in quarantine and adding it to the Pharmacy inventory. This procedure may be supplemented with a trial-specific pharmacy manual or process document(s).

1. **Templates/forms**

IMP01.1 Acknowledgement of Investigational Medicinal Product Receipt

IMP01.2 Pharmacy Accountability Form

1. **Glossary/definitions**

See also: South African Good Clinical Practice (SAGCP) Guideline; ICH Guideline for Good Clinical Practice E6; South African Guide to Good Manufacturing Practice and Good Pharmacy Practice

**Essential Documents**

Documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced (See South African Good Clinical Practice Guideline, Second Edition. 2006. Appendix C).

**Good Manufacturing Practice**

That part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the medicine registration or product specification

**Good Pharmacy Practice**

Standards developed to ensure that all practising pharmacists and other health care professionals providing medicines provide a service of high quality for the public and private sector alike.

**Investigational Medicinal Product (IMP)**

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

**Investigator Site File (ISF)**

Files of Essential Documents held by the Investigator. NB on occasion the [institution/group] may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role.

1. **Responsibilities and procedure**

If the trial is conducted outside of [institution/group] facilities the place where IMP is to be stored (pharmacy or otherwise) should, similarly, be suitable in terms of access control, capacity and equipment (e.g. for temperature monitoring).

Should the IMP involve re-packaging of bulk supplies for individual participants, contact the CRC for advice about whether there is a requirement to comply with regulations over and above Good Pharmacy Practice (e.g. Good Manufacturing Practice).

* 1. **Acknowledgement of IP receipt:**
     1. Arrangements for delivery or collection of IMP are made with the supplier such that its integrity is maintained throughout the transport process.
     2. Upon receipt of IMPs into the pharmacy, the resident pharmacist should notify the trial pharmacist of the delivery. Either the resident or trial pharmacist should acknowledge receipt using the IMP Acknowledgement of Receipt Form (IMP01.1), (or alternative document if required by Sponsor), sending the form back to the appropriate party as required. A separate IMP01.1 is completed for each type and batch of IMP, being as specific as possible while maintaining the integrity of the packaging.
     3. All documentation accompanying or detailing the delivery are noted and filed in the Pharmacy file and/or Investigator Site File (ISF). This may include package inserts, certificates of compliance with GMP Guidelines, certificates of analysis (test products), or product release certificates (reference products). If any expected documents are missing, a designee must notify the pharmacy or Sponsor without undue delay.
     4. If the IMP cannot be immediately added to the pharmacy inventory, it should be labelled with the protocol number, date of receipt and the word “QUARANTINE”.
     5. As soon as the IMP arrives, protocol-specific processes relating to storage of the IMP, such as temperature monitoring, will be commenced.
  2. **Initial IP accountability:**
     1. IMP is added to the pharmacy inventory using an accountability form (IMP01.2).
     2. Work with one type of IMP at a time on a clear, clean surface, taking into account what is known about its toxicity, potency, sensitising potential and risk of cross-contamination. Ensure that audited/un-audited stock is kept separate to avoid confusion.
     3. If there is more than one container of the IMP, ensure expiry dates/batch numbers are the same on each (if different, consult the investigator to ascertain if this is acceptable).
     4. First establish visually if the product on the data sheet appears to be what is supplied. Where containers are received sealed, cross-check labels with the delivery documentation. Ensure details on any outer boxes correlate with wrapping inside the box and that, for instance, blisters are filled appropriately. Where containers are received unsealed, use a clean pill tray or weighing machine (or other equipment depending on the formulation) to verify the contents; count or weigh the IMP ensuring it is consistent in appearance (e.g. colour, size and integrity). The total should be double-checked by the same person or another member of the team.
     5. Any deviations between forms IMP01.1 and 2 should be explored and documented.
  3. Should members of the trial team need to be blinded to any of the above procedures, this should be documented in detail in a Pharmacy Manual or other trial-specific document.

1. **Document history:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |