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

1. **Purpose/scope**

To describe the procedure for returning investigational medicinal products (IMP) to the sponsor or arranging for their destruction for a clinical trial conducted by the [institution/group]. This procedure may be supplemented with a trial-specific pharmacy manual or process document(s).

1. **Templates/forms**

IMP04.1 IMP return form

IMP04.2 IMP receipt for destruction 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).

**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 MCRG 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**
   1. **Return of IMP to sponsor**
      1. An IMP return form (IMP04.1), or alternative if required by the sponsor, is completed by the pharmacist and couriered to the sponsor with the IMP, which is suitably packaged for the journey.
      2. The sponsor should be asked to acknowledge receipt of the IMP by signature/date and return of the form.
      3. The Pharmacy accountability form (IMP01.2) is updated to indicate removal of IMP.
      4. Retention samples, if required for regulatory testing, are left in the IMP store, clearly marked.
   2. **Destruction of IMP**
      1. When written instruction to destroy the IMP is provided by the sponsor, arrangements are made with a suitable drug disposal company to collect it. The IMP should be packaged in suitable outer-packaging in order to keep its own packaging intact. Alternatively, if permission is given by the sponsor, the IMP may be added to the bulk drums in the CRC pharmacy. The latter process should be witnessed by a second member of the team.
      2. The IMP Receipt for destruction form (IMP04.2) is authorised by the PI and signed by both the persons handing over and collecting the package or drum. The original is then sent to the sponsor and a copy filed in the Master File with the certificate or notice of destruction obtained from the drug disposal company.
2. **Document history:**

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