1. **Purpose**

To describe the responsibilities and process for facilitating the generation of labels for, and packaging, investigational medicinal product (IMP) where necessary.

2. **Scope**

The Clinical Research Centre (CRC) will advise whether this document is mandatory for research where UCT’s Faculty of Health Sciences (FHS) is the named sponsor or where CRC facilities are used (CRC SOP 02). In these circumstances the SOP is relevant for CRC pharmacy staff and members of the investigational team who are responsible for packaging and labelling IMP (trial pharmacist or other designee). This SOP may, however, be adapted for use for studies conducted by UCT clinical researchers where UCT is not the sponsor or conducted at other facilities. The information may also be supplemented with a study-specific pharmacy manual.

3. **Templates/forms**

- CRC 07b.1 Label requisition form and printing request
- CRC 07b.2 IMP label
- CRC 07b.3 Packing of IMP form

4. **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
Clinical Research Centre (CRC)
A centre located in UCT's FHS that provides advice and services to researchers in order to produce high quality clinical research. The CRC may agree to take on the role of sponsor for specific studies should certain criteria be fulfilled.

Clinical Trial (of an Investigational product)
Any investigation in human participants (including patients and other volunteers) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining their safety and/or efficacy.

Essential Documents

Good Clinical Practice (GCP)
A standard for clinical trials/studies which encompasses the design, conduct, performance, monitoring, termination, auditing, recording, analysis, and reporting and documentation of clinical trials/studies and which ensures that the trials/studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented and the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. The South African GCP Guidelines are also applicable, in whole or in part, to biomedical research in general.

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.

Printed copies of this SOP should be checked against the original version on the CRC website (www.crc.uct.ac.za)
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
An investigator who is the responsible leader of any site team is the Principal Investigator (PI), a South African-based scientist with sole or joint responsibility for the design, conduct, delegation of responsibilities, analysis and reporting. Sub-investigators are designated and supervised by the PI to perform critical study-related procedures and/or to make important study-related decisions. In the case of a multi-centre trial there must be a local PI attached to each site, while an investigator assigned responsibility for the coordination of investigators at different centres in a multicentre trial is termed a Coordinating (or National) Principal Investigator (CI).

Master File
Files for each project containing key documents (such as Essential Documents for clinical trials). The Master File is in two parts – a Sponsor File and Investigator Site File (ISF).

Standard Operating Procedure (SOP)
Detailed written instructions to achieve uniformity of the performance of a specific function.

Sponsor
An individual, a company, an institution, or an organisation which takes responsibility for the initiation, management, and/or financing of a clinical research project.

5. Responsibilities and procedure
5.1. Label printing
5.1.1. The investigational team member given such responsibility completes a Label requisition form and printing request (CRC 07b.1) adhering to the protocol and South African GCP/GMP requirements. If the CRC Pharmacy is being used, the label must bear the registered name and address: D Tutu Research Pharmacy, J52 OMB Groote Schuur Hospital. Tel: 021 6506965/6.
5.1.2. The completed form(s) is checked by another appropriately trained member of the team before a draft set of labels (CRC 07b.2) is prepared. This should be approved by the PI or trial pharmacist.
5.2. IMP packaging and labelling  When the IMP is already packaged then only the labelling instructions are relevant. This procedure may also be adapted according to the trial design and IMP formulation etc., though the concepts should remain - procedures may alternatively be described in a trial-specific pharmacy manual.

5.2.1. The packing area is appropriately cleaned, windows and doors closed, and extraneous materials removed.

5.2.2. The bulk IMP, required number of appropriately labelled containers, randomisation list, and the Packing of IMP form (CRC 07b.3) are introduced into the packing area.

5.2.3. Treatment dose units are packed per participant (including back-up dose units if required) starting with the first participant number:

5.2.3.1. Dose units are selected from the bulk supply and transferred to the labelled containers according to protocol requirements;

5.2.3.2. A protocol-specific identifier is manually completed on the pre-printed label of the participant-specific container;

5.2.3.3. The information on the label is checked with the randomisation list, if applicable;

5.2.3.4. After all dose units have been packed, the pharmacist and another appropriately trained person must check the packed IMP containers and labels and initial the Packing of IMP form to confirm that containers have been correctly packed and correlate with the randomisation list.

5.2.4. The packed IMP containers and back-up dose units (if any) are separately and securely stored.

5.2.5. The Pharmacy/IMP store accountability form (CRC 07a.1) is updated to indicate the number of packed and unpacked IMPS.

6. Document history:

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