
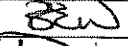
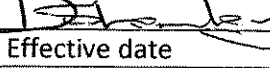


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	<b>University of Cape Town Clinical Research Centre</b>	<b>Standard Operating Procedures</b>
<b>Title</b>	<b>SOP management</b>	
<b>Number</b>	01	
<b>Version</b>	1	

	Name	Title	Signature	Date
Reviewer	B Wright	Project Manager		21 Apr 2015
Authoriser	D Shamley	CRC Director		21/4/2015
			Effective date	21 Apr 2015
			Review date	21 Apr 2018

**1. Purpose**

To describe the procedure for authorship, review, authorisation, issue and control of Clinical Research Centre (CRC) SOPs.

**2. Scope**

This procedure applies to the development of SOPs by UCT's Faculty of Health Sciences (FHS) CRC staff. Some of these will be mandatory (in whole or in part) for investigators and their teams when UCT is the named sponsor of a clinical research project or when CRC facilities are being used. However, all CRC SOPs are also available as templates for adaptation by research teams for use in clinical research studies whether or not UCT is the sponsor.

**3. Templates/forms**

- CRC 1.1      SOP log
- CRC 1.2      SOP Training log

**4. Glossary/definitions****Clinical Research**

Health-related research that involves people, their tissue (e.g. blood samples), behaviour and/or data.

**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.

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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**

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 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.

**Human Research Ethics Committee (HREC)**

An independent body constituted of medical professional and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance on that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. HREC's must be registered and accredited by the National Health Research Ethics Council (NHREC).

**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.

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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).

**Medicines Control Council (MCC)**

A regulatory authority that was established in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 Of 1965) to oversee the regulation of medicines in South Africa. Its main purpose is to safeguard and protect the public by making sure that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.

**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. For clinical trials and other studies where UCT is the Sponsor, or when CRC facilities are used, the CRC leadership will negotiate with the investigator which SOPs are mandatory and/or which study-specific SOPs the investigational team should develop themselves. This will be detailed in the Sponsorship Agreement (CRC SOP 02). Should teams not be able to comply with a mandatory SOP they should discuss this with the CRC immediately rather than deviate from the SOP.

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- 5.2. In addition, CRC SOPs in an editable format are available on request for all UCT clinical researchers. In these circumstances the CRC information (name/ version etc.) is removed, though a reference to the document being a CRC template should remain. It is the investigators' responsibility to ensure that adapted CRC SOPs, or any study-specific SOPs they develop themselves should comply with applicable regulatory and ethical requirements – please speak to the CRC or the study monitor (if relevant) for advice.
- 5.3. The CRC maintains a log of its current and superseded SOPs (CRC 1.1). These SOPs will be reviewed every three years; however deficiencies noted at any time (by any UCT staff member) are dealt with at the earliest opportunity.
- 5.4. The CRC leadership will delegate authorship and review of SOPs to appropriately qualified and experienced personnel. SOPs should be clearly labelled as draft, final etc. during the process.
- 5.5. The author develops a draft/amended SOP using the standard format of this SOP (01) ensuring it is passed onto the reviewer within agreed timelines.
- 5.5.1. CRC SOPs should be consistent with the applicable authorities' requirements (e.g. South African and ICH GCP, MCC and FHS Human Research Ethics Committee, HREC) and be practical/fit for purpose for use within a broad range of research studies and groups.
- 5.5.2. Processes that are mandatory are described using 'should', 'must' etc., while processes that are recommended are described using 'may', 'could' etc.
- 5.5.3. 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, however, these may be adapted due to the scope of clinical research studies supported by the CRC (i.e. clinical trials of investigational products and other types of clinical research).
- 5.6. Once an SOP has been reviewed, a designated member of the CRC staff will check that the format and version are appropriate. It will then be passed to the CRC leadership for authorisation.
- 5.7. CRC staff will receive training where appropriate and sign the SOP Training Log attached to this SOP.

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5.8. A printed version of this SOP and Training Log will be kept at the CRC and will also be saved electronically on the CRC G-Drive.

5.9. The CRC Project Manager or designated staff member will be responsible to keep these files up to date.

5.10 New SOPs are published on the CRC website, and archived on a hard disc.

5.9.1. Investigators of studies sponsored by UCT will be advised whenever a new version of a CRC SOP is published so that they can plan for implementation and training within their research teams. Each investigator/research group leader has a responsibility to track distribution such that their team is working with the current version.

5.9.2. All users of CRC SOPs should ensure that any printed version is the current version on the CRC website.

**6. Document history:**

Version No.	Date	Reviewer	Details of changes
1	n/a	n/a	n/a first version

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	<b>University of Cape Town Clinical Research Centre</b>	<b>CRC 1.1 SOP Log Template</b>
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SOP no.	SOP title	Version/date	Review date
<b>Completed by</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

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## CRC 1.2 SOP Training Log Template

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**University of Cape Town  
Clinical Research Centre**

## CRC1.2 SOP Training Log Template

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