	University of Cape Town Clinical Research Centre	**Standard Operating Procedures**

Title	**Informed consent**
Number	07
Version	3

	Name	Title	Signature	Date
Reviewer	B Wright	Project Manager	BW	5 May 2015
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1. Purpose

To describe the procedure for obtaining informed consent from participants in clinical research studies.

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 investigational team staff involved in the process of obtaining informed consent from participants. This SOP may, however, also be adapted for use for studies conducted by UCT clinical researchers where UCT is not the sponsor.

3. Templates/forms

None

4. Glossary/definitions

See also: South African Good Clinical Practice (SAGCP) Guideline; ICH Guideline for Good Clinical Practice E6; and the UCT Human Research Ethics Committee (HREC) website for extensive ethical and regulatory guidance on the informed consent process and the format and content of informed consent documents.

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.

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. HRECs must be registered and accredited by the National Health Research Ethics Council (NHREC).

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. Development of informed consent documents

5.1.1.Informed consent documents should comply with relevant regulatory and ethical requirements.

For **clinical trials of investigational medicinal products**, the MCC requires the following wording:

"If you have questions about this trial you should first discuss them with your doctor or the ethics committee (contact details as provided on this form). After you have consulted your doctor or the ethics committee and if they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar
SA Medicines Control Council
Department of Health
Private Bag X828
PRETORIA 0001
Fax: see CRC for latest number, e-mail: see CRC for latest email address"

UCT HREC requires that, for **industry-sponsored clinical research**, the consent form must include a simply-worded statement that research-related injuries will be compensated according to the provisions of the SA Department of Health's 2006 SA GCP guidelines, based on the Association of the British Pharmaceutical Industry (ABPI) Clinical Trial Compensation Guidelines.

For **Investigator-initiated research** relying on UCT's No Fault Insurance, the consent form must include: "What if Something Goes Wrong? The University of Cape Town (UCT) undertakes that in the event of you suffering any significant deterioration in health or well-being, or from any unexpected sensitivity or toxicity, that is caused by your participation in the study, it will provide immediate medical care. UCT has appropriate insurance cover to provide prompt payment of compensation for any trial-related injury according to the guidelines outlined by the Association of the British Pharmaceutical Industry, ABPI 1991. Broadly-speaking, the ABPI guidelines recommend that the insured company (UCT), without legal commitment, should compensate you without you having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications. UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request."

5.1.2. Translations of information and consent documents will preferably be sourced through a professional company who certify accuracy of the final versions. However, if budget is not available, they may be produced using competent speakers of both languages (who may or may not be UCT staff) using a forward-backward process. Staff should review the backward translation against the original, and liaise with the translators to correct any inconsistencies. All involved should verify their work through signatures/dates and final versions filed in the Master File.

5.2. Obtaining informed consent

5.2.1. Those obtaining informed consent must be appropriately trained and authorised to do so by the Principal Investigator (PI). Questions from participants (or guardian) should be answered as relevant to the team member's qualification, and noted in the source notes. Information may be given in a group however consent should be obtained in a private place so that participants (or guardian) can voice questions and concerns in confidence.

5.2.2. The participant/guardian (and impartial witness in cases of illiteracy) should be given written information in his/her choice of language. The witness should be given guidance to understand his/her role is to ensure verbal information given to the participant/guardian accurately reflects the document. Tests of literacy and understanding should be documented in the source notes.

5.2.3. Should staff not speak the participant/guardian's language well enough to ensure validity of the consent process and adequate communication throughout the study (in the absence of a translator, for instance), the participant should rather be excluded.

5.2.4. Should consent be given, the investigator and the participant/guardian (or witness) sign and date an original consent form together. Illiterate participants/guardians may also mark in place of a signature. This document is filed in the investigator's file with a copy (or further original) provided to the participant/guardian and another placed in the medical records. Should the participant not have medical records or refuse his/her consent documents it will be stored in the investigator file with a note to that effect.

5.2.5. Errors in signing/dating or inserting specific text in informed consent forms will be addressed as soon as possible by drawing a line through the error (so that the original entry can be seen), and initialling/dating the correction.

5.2.6. At subsequent visits discussions about willingness to continue participation, and additional questions asked and answered, should be noted in the source. Should there be updates to trial information that require re-consent, the process will be repeated with the appropriately approved documents.

5.3. Consent requiring additional attention

5.3.1. The above procedures may need adapting for participants who are pregnant, have mental disabilities or substance-abuse disorders, are in a dependent relationship, incarcerated, highly dependent on medical care (e.g. intensive or emergency care), part of a collective or otherwise vulnerable. Any adaptations should be fully documented.

5.3.2. In the case of minors enrolled into clinical research studies (i.e. children under the age of 18 years) a parent or legal guardian must give permission for the minor to choose. Where a minor is very young, or is factually incapable of exercising a choice, the parent or guardian will choose whether the minor should participate. However, a child is eligible to sign the assent form, depending on their maturity level, which is to be determined by the consenting investigator. To ensure that the consent obtained adheres to the Children's Act 38 of 2005 incorporating the *Judicial Matters Amendment Act 42 of 2013 – Notice 38 in Government Gazette 37254 dated 22 January 2014. Commencement date: 22 January 2014,* the investigator or designee must demonstrate in writing that due diligence has been executed in obtaining documentation/ proof, where applicable of:

- Parent/ child relationship e.g. birth certificate;
- Legal authorization e.g. court order and/ or parenting plans in the case of divorced parents.

1. Document history:

Version No.	Date	Reviewer	Details of changes
1	N/A	N/A	First version
2	16Sep14	E Allen	Added conditions for children to section 5.3
3	31 Mar 15	B Wright	5.1.1 – added reference to GCP guidelines 5.3.2 – changed wording according to UCT Ethics recommendation

Training Log for Informed Consent		
Name:	**Initial:**	**Date:**
