

# WITS HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL) (WITS INDEPENDENT ETHICS COMMITTEE)



## POLICY

**SOP-IEC -010(VERSION 2)**

**IMPLEMENTATION DATE: JANUARY 2010**

<b>SUBJECT</b>	<b>Policy regarding WITS IEC:</b> <ul style="list-style-type: none"> <li>◆ <b>Good Clinical Practice Compliance – (GCP)</b></li> <li>◆ <b>Approval of Clinical Trials for research on Human participants</b></li> <li>◆ <b>Good Clinical Practice approval for all Investigators in Clinical Trials</b></li> </ul>
<b>DIVISION / SCOPE:</b>	<b>Wits Human Research Ethics Committee: (Medical) (Wits Independent Ethics Committee)</b>
<b>REVISION:</b>	IEC Secretariat
<b>PURPOSE:</b>	This statement aims to provide current policy regarding approval of Investigators involved in Clinical Trials that are conducted in WITS Medical and Private institutions requiring the Wits Human Research Ethics Committee approval.
<b>PREVIOUS VERSIONS / (REASON FOR REVISION)</b>	<b>First Version 1.Nov 2008</b> Administrative changes and updates
<b>CONTENT:</b>	<p><b>INDEX</b></p> <p><b>DEFINITIONS AND ABBREVIATION</b> <span style="float: right;"><b>2</b></span></p> <p><b>REFERENCES</b> <span style="float: right;"><b>2</b></span></p> <p><b>3. OVERALL POLICY STATEMENT</b></p> <p style="padding-left: 20px;">The Approval of Investigators in clinical Trials</p> <p style="padding-left: 20px;">3.1 Comprehensive training in Internationally accepted GCP</p> <p style="padding-left: 20px;">3.2 Comprehensive training in the GCP principles specific to South African requirements <span style="float: right;"><b>2</b></span></p> <p style="padding-left: 20px;">3.3 A formal assessment of the knowledge of individuals <span style="float: right;"><b>3</b></span></p> <p style="padding-left: 20px;">3.4 The Wits HREC (M) is not in favor of on-line courses</p> <p style="padding-left: 20px;">3.5 The minimum requirement</p> <p style="padding-left: 20px;">3.6 investigators meetings are not accepted</p> <p><b>4. REFER TO GUIDELINES:</b></p> <ul style="list-style-type: none"> <li>◆ FDA Guidelines – OHRP (Office of the Human Rights Protection)</li> <li>◆ ICH GCP Guidelines</li> <li>◆ Declaration of Helsinki 2008</li> <li>◆ SA GCP Guidelines 2006 Second Edition <span style="float: right;"><b>3</b></span></li> </ul>
<b>APPROVALS:</b>	<p style="text-align: center;"><b>Signature of Chairperson / Deputy Chairperson of IEC:</b></p> <p style="text-align: center;"><i>Prof P Cleaton-Jones / Prof M Vorster</i></p> <p style="text-align: right;"><b>Date:</b></p>



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### 1. Definitions and Abbreviations

ADR	Adverse Drug Reaction
CFR	Code of Federal Regulations (USA)
Clinical Investigation	Means any experiment that involves a test article and one or more human participants. The terms "research", "clinical research", "clinical study", "clinical trial" and "clinical investigation" are considered synonymous for WITS IEC policies and procedures.
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practices
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee (ICH GCP term)
IRB	Institutional Review Boards (USA term for IEC)
MCC	Medicine Control Council (RSA)
SAE's	Serious Adverse Events
SAGCP	Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006)
SOPs	Standard Operating Procedures
WHC	WITS Health Consortium
WITS	Witwatersrand

### 2. References

- ◆ FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards
  - ◆ <http://www.hhs.gov/ohrp/policy/>
- ◆ International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline (October 2008)
  - ◆ Declaration of Helsinki 2008
  - ◆ <http://www.wma.net/e/ethicsunit/helsinki.htm>
  - ◆ <http://www.wma.net/e/policy/b3.htm>
- ◆ South African Guidelines for Good Clinical Practice Guidelines 2006 Second Edition
  - ◆ [http://www.doh.gov.za/docs/policy/trials/trials\\_02.html](http://www.doh.gov.za/docs/policy/trials/trials_02.html)
- ◆ 21 Code of Federal Regulations Part 56 – Institutional Review Boards
- ◆ 21 Code of Federal Regulations Part 50 – Protection of Human Participants
- ◆ MRC Guidelines on Ethics for Medical Research, Revised Edition, 1993

### 3. Overall policy statement

One of the primary criteria in all Clinical Trials receiving ethical approval passed by the Wits Human Research Ethics Committee for Investigators involved in the conduct of clinical trials is the patient's well being, safety and benefits / risks, as outlined in the Declaration of Helsinki 2008.

This principle is applied when assessing the relevant Investigator's experience in the conduct of clinical trials, their workload, publications and this includes reviewing compliance with International and National Good Clinical Practice Guidelines.

The South African Department of Health, Medicines Control Council requires Good Clinical Practice (GCP) Training for all Investigators in Clinical Trials, and that GCP training be renewed every three (3) years.

As yet, there are no National Guidelines for the content of GCP courses. Until these are available the Wits Human Research Ethics Committee (Medical) will note courses completed by Investigators without approval of the content of the individual courses.

What the Wits HREC (M) believes should be a minimum requirement for GCP courses should be:



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- 3.1 **Comprehensive training in Internationally accepted GCP principles**
    - ◆ FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards
    - ◆ International Conference on Harmonization (ICH) Good Clinical Practices (GCP) Guideline (October 2008), and
    - ◆ Declaration of Helsinki 2008
  - 3.2 **Comprehensive training in the GCP principles specific to South African requirements**
    - ◆ Guidelines for Good Clinical Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006) Second Edition.
  - 3.3 **A formal assessment of the knowledge of individuals completing GCP courses.**
  - 3.4 **The Wits HREC (M) is not in favor of on-line courses believing that the interaction in face to face courses is important.**
  - 3.5 **The minimum requirement for Investigators involved with clinical trails that a GCP course be attended every three (3) years.**
    - 3.5.1 **Information of GCP courses to be attached to CV's submitted with HREC applications.**
  - 3.6 **Investigators meetings are not accepted by the The Wits HREC (M) as GCP training.**
- 4 **REFER TO SOP-IEC-004**  
Policy regarding WITS IEC management of any compliance queries and/or deviations identified at a WITS / Private Research Sites

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**Postscript: Ref: IRB Details – [www.witshealth.co.za](http://www.witshealth.co.za) –Select Ethics (top left) Doc 170 Item 6. The Wits Human Research Ethics Committee is registered as an institutional review board (IRB) with the Office for Human Research Protections (OHRP) of the USA Dept of Health and Human Services;**

- ◆ **IRB Organisation Identifier:** IRB000011223
- ◆ **The W HREC unique Federal Assurance Number is** FWA00000715
- ◆ **The unique Organisation Number is** IORG0000862

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**EXTRACT FROM MINUTES HELD BY THE  
HUMAN RESEARCH ETHICS COMMITTEE  
HELD ON 30 MAY 2003**

**Venue: PPS Boardroom, Faculty of Health Sciences, Medical School,  
University of the Witwatersrand**

- 4.3 **GOOD CLINICAL PRACTICE (GCP) COURSE FOR CO/SUB INVESTIGATORS:**
- ◆ **The HREC required from January 2003 that all Principal Investigators attend a GCP Course before the Ethics Approval is granted for the Clinical study.**
  - ◆ **The HREC decided that by January 2004 that all Co and Sub Investigators attend a GCP Course before the Ethics Approval is granted for the Clinical study.**
  - ◆ **The HREC recommends that all Principal / Co and Sub Investigators attend a GCP Course.**
  - ◆ **Discussed and Approved.**