

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

## POLICY



SOP-IEC-004 (VERSION 4)

IMPLEMENTATION DATE JANUARY 2010

<b>SUBJECT:</b>	<b>Policy regarding WITS IEC management of any compliance queries and/or deviations identified at a WITS / Private trial site.</b>														
<b>DIVISION / SCOPE:</b>	HUMAN RESEARCH ETHICS COMMITTEE: (Medical) (WITS INDEPENDENT ETHICS COMMITTEE)														
<b>AUTHOR: REVISED BY:</b>	Wits Clinical Research Division														
<b>PURPOSE:</b>	This policy aims to provide an overall description of the procedure to be followed by the WITS IEC relating to identified queries and/or deviations regarding Clinical Trials that are conducted in the WITS Medical Institutions and Wits approved private sites.														
<b>PREVIOUS VERSIONS / (REASON FOR REVISION)</b>	SOP-IEC-004-v1;2; and 3 Updating of Forms														
<b>CONTENTS:</b>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">1. Definitions And Abbreviations</td> <td style="text-align: right;">2</td> </tr> <tr> <td style="padding-left: 20px;">2. References</td> <td style="text-align: right;">2</td> </tr> <tr> <td style="padding-left: 20px;">3. Overall Policy Statement</td> <td style="text-align: right;">2</td> </tr> <tr> <td style="padding-left: 40px;">3.1 Query/Deviation Identified By Wits Iec</td> <td style="text-align: right;">3</td> </tr> <tr> <td style="padding-left: 40px;">3.2 Query/Deviation Identified By Sponsor</td> <td style="text-align: right;">4</td> </tr> <tr> <td style="padding-left: 40px;">3.3 Sponsor Request Co-Monitoring</td> <td style="text-align: right;">5</td> </tr> <tr> <td style="padding-left: 20px;">4. Attachment: <i>Flow Chart</i></td> <td style="text-align: right;">6</td> </tr> </table>	1. Definitions And Abbreviations	2	2. References	2	3. Overall Policy Statement	2	3.1 Query/Deviation Identified By Wits Iec	3	3.2 Query/Deviation Identified By Sponsor	4	3.3 Sponsor Request Co-Monitoring	5	4. Attachment: <i>Flow Chart</i>	6
1. Definitions And Abbreviations	2														
2. References	2														
3. Overall Policy Statement	2														
3.1 Query/Deviation Identified By Wits Iec	3														
3.2 Query/Deviation Identified By Sponsor	4														
3.3 Sponsor Request Co-Monitoring	5														
4. Attachment: <i>Flow Chart</i>	6														
<b>APPROVALS:</b>	<b>Signature of Chairperson of IEC: Date:</b> <i>Prof P Cleaton-Jones</i>														

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### 1. DEFINITIONS AND ABBREVIATIONS

GCP	Good Clinical Practices
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee (ICH GCP term)
SOPs	Standard Operating Procedures
WHC	WITS Health Consortium
WITS	Witwatersrand
WCR	Wits Clinical Research Division

### 2. REFERENCES

- ◆ International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline
- ◆ Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006)
- ◆ Declaration of Helsinki 2008

### 3. Overall policy statement

The HUMAN RESEARCH ETHICS COMMITTEE: (Medical) WITS INDEPENDENT ETHICS COMMITTEE) {WITS IEC} aims to manage any queries and/or deviations regarding Clinical Trials identified at the WITS Medical Institutions and private sites approved by the Wits IEC in accordance with the following requirements

- ◆ International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline (June 1996 Section 3)), and
- ◆ Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006)
- ◆ Declaration of Helsinki

This document will be submitted to investigators and sponsors who require more information about the operation of the WITS IEC.

**The IEC Secretariat will handle all administrative functions of the WITS IEC.**

#### 3.1. QUERY/DEVIATION IDENTIFIED BY WITS IEC

All Phase I to Phase IV clinical trials that are conducted in the WITS institutions as well as those submitted to be conducted in private practice must be approved by the WITS IEC prior to the enrolment of any participants. The Wits Clinical Research (WCR) Division will review and monitor trials at any time on behalf of the WITS IEC, who will also commission spot audits of sites from time to time. Any deviation from the principles and guidelines of good clinical practice and/or the protocol will be put before the Ethics Committee for action that may include, but not be limited to, disqualification as an investigator and rehabilitation before being accepted as an investigator in other studies.

The Chairman of the WITS IEC, or his representative, together with a representative from the WCR, will meet with the Sponsor Company to discuss the deviation, and jointly formulate an action plan before meeting with the investigator and taking any action.

Where deemed necessary by the WITS IEC, the WCR and the Sponsor Company, the WITS IEC will appoint and send an independent auditor/Wits IEC monitor to the problem site for an audit/monitoring visit dependent on the nature of the problem. The audit/monitoring visit findings will be reported to the WITS IEC. Upon receipt of the findings, the WCR acting on behalf of the WITS IEC will set up a meeting with the appropriate sponsor company to discuss correctional measures to be implemented.

Depending on the severity of the deviation, Investigators will either attend a meeting with their Head of Department, the Chairman of the WITS IEC and a representative from the WCR, or be required to address the full IEC Committee at a meeting of the Committee. The Sponsor Company will, as a matter of course be informed of the meeting and may also attend the meeting if they choose to do so.

Should it be deemed necessary, a site might be disqualified from future clinical research until appropriate rehabilitation has taken place.

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### 3.2. QUERY/DEVIATION IDENTIFIED BY SPONSOR

Should a sponsor company identify a problem at a WITS trial site, this should be communicated to the Wits WCR Division who will refer the matter to the WITS IEC.

The WITS IEC will appoint and send an independent auditor or the WITS IEC monitor to the problem site for an audit or monitoring visit, depending on the severity of the reported problem. The audit/monitoring findings will be reported to the WCR and the WITS IEC in writing. Upon receipt of the audit/monitoring findings, the WCR acting on behalf of the WITS IEC will set up a meeting with the appropriate sponsor company to discuss correctional measures.

Depending on the severity of the deviation, Investigators will either attend a meeting with their Head of Department, the Chairperson of the WITS IEC and a representative from the WCR, or be required to address the full IEC Committee at a meeting of the Committee. The Sponsor Company will be notified of the meeting and may attend it if they choose to do so.

Should it be deemed necessary, a site might be disqualified from future clinical research until appropriate rehabilitation has taken place.

### 3.3. SPONSOR REQUESTING CO-MONITORING

Where a site is inexperienced or under rehabilitation, the WITS IEC will offer and provide co-monitoring functions by the IEC monitor.

Should a sponsor company request the ethics monitor to co-monitor a site with the sponsor's monitor/CRA, this request should be made in writing to the WCR who will refer the matter to the WITS IEC.

A representative from the WCR, acting on behalf of the WITS IEC, will meet with the Sponsor Company (CRA/CRM) to discuss the necessity and reason for the co-monitoring. A written confirmation from the WCR, appointing an appropriate monitor and/or monitoring schedule, will be sent to the Sponsor.

The co-monitoring findings will be reported to the WCR and the WITS IEC in writing.

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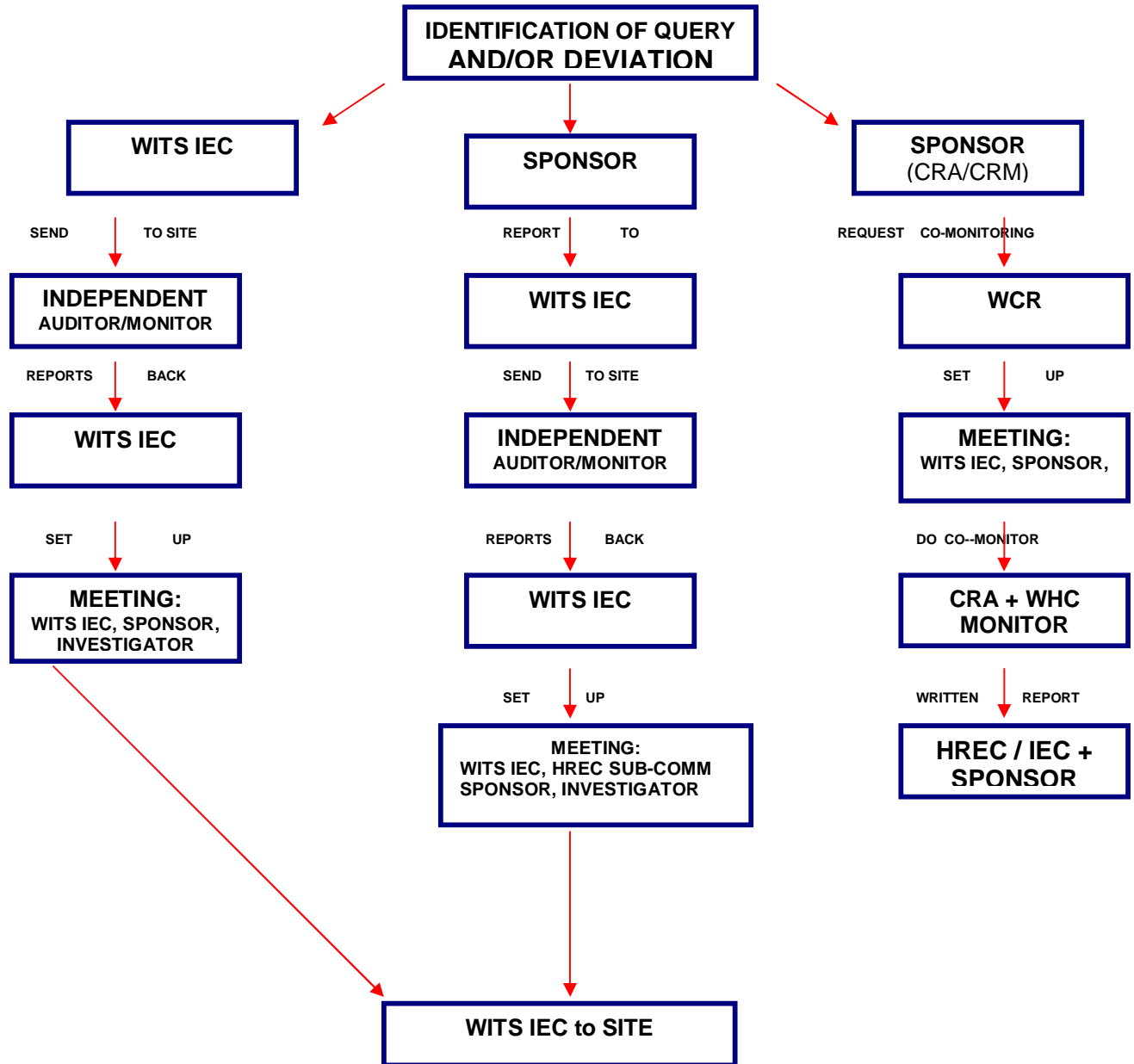
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### 4. ATTACHMENT:

### FLOW CHART



**CORRECTIVE MEASURES**  
REHABILITATION  
DISQUALIFICATION

#### ROLE OF WITS CLINICAL RESEARCH DIVISION:

ADMINISTRATIVE FUNCTIONS  
GUIDANCE  
TRAINING  
SOLVING LOGISTIC PROBLEMS