

**WITS HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)
(WITS INDEPENDENT ETHICS COMMITTEE)
STANDARD OPERATING PROCEDURE**



SOP-IEC – 001 (VERSION 6)

IMPLEMENTATION DATE: JANUARY 2010

SUBJECT:	Procedure for the Approval of Research on Human Participants by the WITS Independent Ethics Committee																		
DIVISION / SCOPE:	HUMAN RESEARCH ETHICS COMMITTEE: (Medical) (WITS INDEPENDENT ETHICS COMMITTEE)																		
AUTHOR: REVISION:	Wits Clinical Research Division																		
PURPOSE:	<p>This procedure describes the process to be followed by the WITS IEC for the approval of Research on Human Participants at WITS institutions and private practice applications to ensure that the approvals provided by the WITS IEC are in compliance with the following requirements:</p> <ul style="list-style-type: none"> ◆ Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006) ◆ International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline (June 1996 Section 3), and ◆ The applicable FDA requirements for Institutional Review Boards (21 CFR Part 56). 																		
PREVIOUS VERSIONS / (REASON FOR REVISION)	<p>SOP-IEC-001v1; 2; 3; 4 and 5</p> <p>Changes in working methodologies of IEC, updating of forms</p>																		
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APPROVALS:	<table border="0"> <tr> <td>Signature of Chairperson of IEC:</td> <td>Date:</td> </tr> <tr> <td><i>Prof P Cleaton-Jones</i></td> <td></td> </tr> </table>	Signature of Chairperson of IEC:	Date:	<i>Prof P Cleaton-Jones</i>															
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1. DEFINITIONS AND ABBREVIATIONS

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.
CTD	Clinical Trials Division
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IRB	Institutional Review Boards (USA term for IEC)
IEC	Independent Ethics Committee (ICH GCP term)
SAGCP	Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2000)
MCC	Medicine Control Council (RSA)
WHC	WITS Health Consortium
WITS	Witwatersrand
WCR	Wits Clinical Research Division

2. REFERENCES

- International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline (June 1996 Section 3)
- 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
- Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006)
- Declaration of Helsinki 2008

3. SCHEDULING WITS IEC MEETINGS

All meetings are to be held in the Boardroom of the Faculty for Human Sciences the last Friday of the month or the nearest Friday if a public holiday intervenes.

Responsible person	Action to be taken
Chairperson 1	Propose dates for the following years’ meetings at the last meeting in November of each year.
Members present at November WITS IEC Meeting 2	Agree on dates of meetings for following year as proposed by Chairperson if no objection to proposed dates is made. If there are problems with the proposed dates alternatives should be discussed and agreed upon.
Chairperson 3	The WITS IEC Secretariat is then requested to notify all relevant persons of the proposed dates for the following year, to post on the WHC web page.

CHANGES TO DATES OF WITS IEC MEETINGS

Member requesting change (if applicable) 1	Address proposal for change of meeting date giving reasons for proposed change to the Chairperson.
Chairperson 2	Ensure that the proposed revision of a meeting’s date is addressed at the next WITS IEC Meeting. If changes are agreed upon, WHC Clinical Trials Division (CTD) is to be requested to notify all relevant persons that received the original schedule of dates in writing as soon as possible.



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NOTIFICATION OF MEMBERS OF WITS IEC MEETINGS

IEC Secretariat	1	<p>The Agenda, Minutes of the previous meeting and applicable accompanying documents for example</p> <ul style="list-style-type: none"> ◆ Recertification Application Forms ◆ HREC Application form ◆ Protocol Summary/Amendment Summary
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4. PROCEDURE FOR MEETING AND APPROVAL OF HUMAN RESEARCH TO BE CONDUCTED AT WITS INSTITUTIONS AND IN PRIVATE PRACTICE

The IEC Secretariat will handle the administration of documents that are received for IEC approval according to their procedures. Their procedures require that the following documentation be available for application of IEC approval:

- IEC Application Forms
- Protocols / Amendments
- Investigator's Brochures
- Protocol Summaries
- Patient Information Sheets (must be WITS specific and include ABPI clause)
- Patient Informed Consent Forms
- Separate Patient Information and Informed Consent form for taking of samples for future testing
- Summary of Patient Visits and Payment Schedule
- Commitments and Declaration of Investigators
- Investigator's Curriculum Vitae
- Financial Agreement

If advertisements and/or questionnaires are to be used for the clinical investigation, these must also be approved by the WITS IEC prior to use thereof.

Responsible person	Action to be taken	
Chairperson or designated Deputy	1	Supply the IEC Secretariat with the names of two Assessors for each protocol when the Draft Agenda for the next IEC Meeting is received from the IEC Secretariat.
Chairperson and Assessors	2	Review the protocol and other documents received from the IEC Secretariat in detail prior to the IEC Meeting.
Assessors and IEC Secretariat	3	The Consent/Patient Information Leaflet is to be checked for compliance with SAGCP, ICH GCP section 4.8.10 and 21 CFR Part 50.25 in accordance with the latest version of the IEC Secretariat Checklist
Chairperson or designated Deputy	4	The WITS IEC Chairperson is to chair the WITS IEC Meeting. Representatives from the IEC Secretariat will be responsible for arranging the meeting and keeping minutes of the meeting.
	5	Minutes of the last meeting are to be confirmed as correct.
Assessors	6	Present report on the protocol reviewed from an ethical perspective taking into account the reports from the Expert Reviewers of the Protocol Review Committee who review from a scientific, clinical and safety perspective, regardless of whether the study is being conducted in a WITS institution or private practice.



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All members present at Meeting	7	Discuss concerns, recommendations and queries relating to the presented protocol. If queries are unresolved at the meeting, the IEC Secretariat will address these with the investigator and sponsor after the meeting. <i>The answers to the queries are forwarded to the expert Reviewers for their approval. The responses are then collated for Chairman's approval.</i>
Assessors	8	Timeline for Review. Reviewers are required to be submitted to IEC Secretariat within Seven working days from date of receipt
Chairperson	9	Call for vote on approval/non-approval of protocol if all issues relating to the protocol are resolved during the meeting.
All members present	10	Vote on approval/non-approval of each protocol reported on by the Expert Reviewers. Only a quorum, as defined in SOP-IEC-003, may approve a protocol. The decision of approval must be based on the criteria for approval of research, SAGCP pg 41 and ICH-GCP. The amount of risk to patients is considered and discussed by the committee with regards to benefit to the patient, potential risk due to the study drug, study procedures, concomitant therapy, concurrent diseases and the potential effect of the study thereon, implications in terms of vulnerable populations.
IEC Secretariat	11	Prepare draft minutes of meeting according to the IEC Secretariat procedures. The minutes should contain the following information: <ul style="list-style-type: none"> • Actual attendance at meeting • Results of voting by members • Actions taken by the IEC • Written summary of discussion of controversial issues • Resolution of these issues
Chairperson	12	Review Draft minutes and make corrections as necessary then forward to IEC Secretariat for finalisation.
IEC Secretariat	13	Send approval letters and address unresolved queries with the Investigators and or sponsors as required according to the SOP-CTD-002.
WITS IEC Secretariat	14	Ensure that all documentation is archived

4. ATTACHMENTS

- ◆ Letter to avoid delays
- ◆ WITS IEC Secretariat Checklist
 - Informed Consent Checklist
 - Checklist generated from WCR Database acknowledging receipt of Ethics submission

