

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



SOP-IEC – 003 (VERSION 6)

IMPLEMENTATION DATE: JANUARY 2010

SUBJECT:	Composition, selection of a quorum for voting of the WITS IEC	
DIVISION / SCOPE:	HUMAN RESEARCH ETHICS COMMITTEE: (Medical) (WITS INDEPENDENT ETHICS COMMITTEE)	
AUTHOR:	Wits Clinical Research Division	
REVISION:	IEC Secretariat	
PURPOSE:	<p>This procedure describes the process to be followed by the WITS IEC for the ongoing review of Research on Human Participants at WITS approved institutions to 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)), ◆ SAMRC Guidelines on Ethics for Medical Research, Revised Edition, 1993 and ◆ The applicable FDA requirements for Institutional Review Boards (21 CFR Part 56). 	
PREVIOUS VERSIONS / (REASON FOR REVISION)	SOP-IEC-003v1;2; 3; 4 and 5 Changes in working methodologies of IEC, updating of forms	
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APPROVALS:	Signature of Chairperson of IEC: <i>Prof P Cleaton-Jones</i>	Date:



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1. DEFINITIONS AND ABBREVIATIONS

CFR	Code of Federal Regulations (USA) 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.
Clinical Investigation	
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)
SAE's	Serious Adverse Event Reports
WHC	WITS Health Consortium
WITS	Witwatersrand

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 (2000)
- ◆ [Declaration of Helsinki 2008](#)

3. COMPOSITION OF THE WITS IEC

The composition of the WITS IEC shall be such that it consists of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research and includes consideration for race, gender, cultural background and sensitivity to such issues as community attitudes. The membership should reflect the demographic profile of the population of South Africa.

If research in vulnerable participants such as children, prisoners, pregnant women, handicapped or mentally disabled persons is being considered, one or more individuals who are knowledgeable about and experienced in working with those participants should be present at the meeting.

The WITS IEC shall comply with SA GCP Guidelines and shall include:

- At least five members
- At least one member whose primary area of interest is in a non-scientific area.
- At least one member who is independent of WITS and the trial site.
- The independent member should ideally attend every meeting.
- Members of both sexes and differing professions.
- At least one member who is legally trained.

Three Deputy Chairpersons will be nominated that may act on behalf of the Chairperson in the absence of the chairperson.

Only members who are independent of the investigator and the sponsor of the trial and are present during the discussion of the research shall vote/provide opinion on a trial-related matter. Members with a conflict of interest or who are involved in the trial, will recuse themselves whilst the trial is discussed and the trial is voted for by the IEC Committee.



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Non-members with expertise in special areas may be requested to attend the WITS IEC Meeting for assistance. The investigator may also attend the discussion relating to his/her protocol.

A list of IEC members and their qualifications shall be maintained for each WITS IEC Meeting and will be distributed together with the WITS IEC Approval notification by the IEC Secretariat.

4. SELECTION OF WITS IEC MEMBERS

A new member of the WITS IEC may be required to replace a member that leaves, or meet requirements of the SA GCP, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guideline and/or Food and Drug Administration of the U.S.A regulations.

Curriculum vitae are obtained and distributed to IEC members for prospective new members by the Chairperson. The prospective candidates are discussed at the IEC Meeting following their agreement to stand for IEC membership. Once the IEC members have agreed on the new IEC member, a curriculum vitae and motivation are sent by the Chairperson to the Research Office of the University for final approval and appointment.

5. WITS IEC QUORUM

A quorum will be constituted by a minimum of five members, of which, one member who is a non-medical member, and one of the non-medical members to preferably be a non-affiliate.

In order for a clinical investigation to be approved, it shall receive the approval of a majority of those members present at the meeting.

6. Attachments

None

