

**STANDARD OPERATING PROCEDURE
APPROVAL PROCESS**
(SA GCP Guidelines 2006 : 1.2.7 pg 10; 8.5 pg 59)

Regulatory Framework :

Bill of Rights of the Constitution of South Africa
National Health Act

Guidance Documents

Health Professions Council of SA
Ethics in Health Research: Principals, Structures and Processes
European Association of Palliative Care
South African Good Clinical Practice Guidelines – 2006
Declaration of Helsinki
The Belmont Report
Office of Human Research Protections: 45CFR46; 21CFR50; 21CFR56
CIOMS
ICH-GCP

Approval Process

Electronic copies of the form *Application to Conduct Research* submitted to the Administrator who circulates it to the Committee together with the form *Reviewer Evaluation* which has been headed with the study title, Principal Investigator's name, and protocol reference no.

Administrative Process :

Protocols for approval need to be submitted by the 7th of each month
To the Committee by the 12th of each month
3 weeks for Committee review.

The Administrator checks the submitted documentation for accuracy and completeness. In addition, the Administrator checks the Information to Participants documents for compliance with SA GCP and 'Ethics in Health Research: Principals, Structures and Processes' guidance and 45CFR46 (USA) and / or other pertinent regulatory policy documents.

Scheduling of REC Meetings

Meetings are scheduled to be held on the last Tuesday of each month by teleconference. Face-to-face meetings will be held at least twice per year.

Scheduled meetings will only be conducted when a quorum is present. Co-opted members are included in the decision on the quorum (60%). Decisions will be determined by consensus (general agreement). Where general agreement does not exist, consensus will be undermined and the decision will be arrived at by vote.

Members will be notified of the scheduled dates no later than the second week of January.

Chairperson : Proposes dates for Committee consideration for the following years' meetings at the last meeting in November of each year.

Changes in dates of meetings : Proposed changes, with reasons, to be submitted to the Chairperson in writing. The REC Administrator circulates to the Committee to ascertain availability of Committee. Confirmation of change, or otherwise, is reported to Committee as soon as possible following final decision.

Committee members who, for any reason, are unable to attend a forthcoming meeting will inform the Ethics Administrator at least 3 weeks before the meeting.

Administration :

The Agenda for scheduled meetings, together with supporting documentation, will be circulated to Committee at least 14 days prior to the meeting.

The following documentation (as appropriate) is to be made available at the meeting :

1. Protocols
2. Amendments
3. Recertification
4. Adverse Events
5. Investigator's Curriculum Vitae
6. Trial/study protocol(s)
7. Written information to be provided to participants
8. Written informed consent form(s)
9. Participant recruitment procedures
10. Investigator's brochure (IB) (if applicable)
11. Safety information (if applicable)
12. Researcher's current curriculum vitae and / or other documentation evidencing qualifications
13. Any other documentation that the Committee may require to fulfill its responsibilities e.g. advertisements

Further documentation may be required after initial ethics approval has been granted such as Data Safety Monitoring Boards (DSMBs) reports or other monitoring Committee / Board reports; updated documentation where applicable.

Every Committee member reviews the protocol in full and the Chair will nominate one of the members when the protocol is sent out for review to give a synopsis of the study together with the positive and negative aspects of the proposed research, any contribution the study brings to science and any ethics and safety issues of concern. Particular attention is paid during the review process given that the population that is being researched is may be vulnerable. The study is then discussed by the full Committee at the meeting.

Concerns, recommendations and queries relating to the presented protocol are discussed and these are submitted to the Investigator in writing. The responses to queries raised are then submitted to the Committee for approval.

The Administrator prepares draft Minutes and details actual attendance at meeting, gives a summary of the discussion that took place, and notes the queries that are to be addressed by the Principal Investigator. All controversial issues are detailed together with how the issue was resolved. If consensus is not reached on a study, voting would have had to take place and the results of voting by members is recorded - those for, against and abstentions.

The Chairperson reviews the draft Minutes and makes corrections as necessary and forwards to the Administrator for finalization.

The Administrator drafts letters of queries to the Investigator for signature by the Chair, and compiles and distributes letters of approval for all other decisions that were taken at the meeting - approvals of amendments, recertifications, etc.

The Administrator then files all correspondence and Minutes together with the signed Attendance form for the meeting.