

MEDICINES CONTROL COUNCIL



GOOD CLINICAL PRACTISES: *EMERGENCY TROLLEY*

TO ALL APPLICANTS

Kindly be advised that the Medicines Control Council has resolved that Principal Investigators at all sites conducting clinical trials must ensure that they have emergency trolleys on site with immediate effect, irrespective of whether or not the site is on the premises of a hospital.

The Medicines Control Council has noted with concern that an increasing number of GCP inspections conducted by Inspectors reflects a lack in the availability of an emergency trolley at the site where the clinical trial is conducted. Your attention is invited to the section 3.3, 3.4 and 3.11 of the *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa: Second Edition (2006)*:

3.3 (ADEQUATE RESOURCES)

The principal investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

3.4 (MEDICAL CARE OF TRIAL PARTICIPANTS)

During and after a participant's involvement in a trial, the PI/investigator/institution should ensure that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial.

3.11 (SAFETY ISSUES)

The principal investigator is responsible for ensuring that adequate provisions are made for dealing with any expected and unexpected adverse events that may occur in the study participants.

Dr J C Gouws
REGISTRAR OF MEDICINES