

AMENDMENTS TO APPROVED PROTOCOLS AND OTHER DOCUMENTS

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

A summary explaining the reasons for the change/s to be made must be submitted together with the amended page/s of the protocol or other documentation – all changes to be highlighted on the amended page/s.

The summary must indicate the previous text and the new text, for example, “CHANGED FROM” and “CHANGED TO” and referenced with the page number/s of where in the original protocol the text can be found.

Examples of Amendments :

MINOR AMENDMENTS

1. Tightening of inclusion criteria
2. Tightening of exclusion criteria
3. Additional Investigators
4. Additional Sites
5. Change in the Informed Consent
6. Change in the Investigator’s Brochure
7. Change in background information
8. Extension of period of study
9. Other changes that do not affect neither study design nor analysis / results
10. Administrative changes

MAJOR AMENDMENTS

1. Relaxation of inclusion criteria
2. Relaxation of exclusion criteria
3. Change in Objectives / Rationale of study
4. Change in study design
5. Relaxation of standards for data analysis

Submission process :

Minor amendments can be submitted at any time and will be reviewed by Exco and any decisions taken will be ratified at the next meeting of the REC (either face-to-face or teleconference);

Major amendments are to be submitted by the 7th of each month and will be sent out for full Committee review at the next meeting of the REC (either face-to-face or teleconference);

If there is **any uncertainty** regarding the amendment the decision will be made by Exco and the appropriate procedure followed.