

**STANDARD OPERATING PROCEDURE
RECERTIFICATION**
(SA GCP Guidelines 3.14; pg 36)

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
MCC Guidelines : www.mccza.com
South African Good Clinical Practice Guidelines – 2006
Office of Human Research Protections : 21CFR50
CIOMS
ICH-GCP

Ethics approval is valid for one year only.

A “Recertification of Protocol” form needs to be completed a couple of months prior to the anniversary of the approval date.

The following documents must be submitted with the completed Recertification of Protocol form :

1. Current Protocol
2. Current Informed Consent Documents

New consent forms / amendments requiring approval by the HPCA Research Ethics Committee must be submitted separately AND NOT as part of the recertification procedure.

Documents for recertification purposes must be submitted to the HPCA Research Ethics Committee.

Recertification will be approved by the Exco and ratified at its next scheduled meeting.