



APPLICATION FOR ADDITIONAL INVESTIGATOR(S) OR CHANGE OF INVESTIGATOR(S) AND APPLICATION FOR ADDITIONAL SITES

Study title	
Approved Protocol No., Version and Date	
SAHPRA Reference No.	
Investigational Product(s)	
Name of Sponsor:	
Name of Applicant:	
Name, designation and qualifications of person representing the Applicant - Local Contact Person for all further correspondence. (Address, Telephone, Fax No., Cell No. and E-mail address)	
Date of Application:	

Check-list

<input type="checkbox"/>	Cover Letter (describing the change)
<input type="checkbox"/>	Two copies of clinical trial application for administrative amendment (CTF3) (fully completed copies)
<input type="checkbox"/>	Investigator documents: SAHPRA format CV, Workload form, Declaration form, GCP certificate, HPCSA annual registration document, Medical malpractice insurance and dispensing license (if applicable)
<input type="checkbox"/>	Additional site staff documents: SAHPRA format CV, Declaration form, GCP certificate and Proof of registration with statutory body (e.g. SAPC, SANC, HPCSA), if applicable
<input type="checkbox"/>	Emergency trolley details (for additional site applications)
<input type="checkbox"/>	Two Labelled CD-ROM (List of files submitted on CD-ROM)
<input type="checkbox"/>	Any additional information (list them), if applicable
<input type="checkbox"/>	Proof of payment

NB: Incomplete documentation or sub-standard submissions will be rejected.

Application should be ring-bound. Lever arch files will not be accepted.

APPLICATION FOR APPROVAL OF:

- ADDITIONS AND/OR CHANGES IN INVESTIGATOR(S) AT APPROVED SITE**
- ADDITIONAL SITE (S)**

SECTION 1: ADMINISTRATIVE

PART 1: APPLICANT DETAILS	
1.1 Name, physical address, email address, telephone number and fax number of the Applicant.	
1.2 Name, physical address, email address, telephone number and fax number of the CRO representing sponsor as Applicant or Local Sponsor Company details (if applicable).	
1.3 National Principal Investigator name, address, telephone number and fax number.	

PART 2: TRIAL PARTICULARS (original application)	
2.1 Date of approval of original protocol.	
2.2 Details of investigators and sites in South Africa already approved for this trial (Name of site(s), Investigators, Designation - Principal Investigator or Sub-Investigator).	
2.3 Number of participants in South Africa already approved for this trial	

SECTION 2: ADMINISTRATIVE AMENDMENT

PART 3: INVESTIGATOR DETAILS	
3.1 Name and address of additional Investigator(s) / Changes to Investigators.	
3.2 For Investigators who have not previously been in clinical trials, proof of adequate training and experience to properly conduct the study must be provided.	
3.3 Summarise other ongoing/planned studies at this site involving this investigator (give details of indication, phase, study status, number of participants intended, number of participants already enrolled, whether the investigator is involved in research in a full-time or part-time capacity, and any other detail that may affect the capacity of the site at any one time).	

PART 3: INVESTIGATOR DETAILS	
3.4 Details of Ethics Committee(s) who will approve investigator(s).	
3.5 Date of application to Ethics Committee.	
3.6 Date of approval by Ethics Committee.	
3.7 Is CV for additional Investigator(s) attached (list) YES <input type="checkbox"/>	
3.8 Is the Declaration of Intent attached (list) YES <input type="checkbox"/>	

PART 4: CAPACITY OF THE SITE	
4.1 Describe how the site is structured so as to be able to take on the work for which this application is being made. (Give details of support staff, facilities, emergency trolleys, back up and any other relevant infrastructure).	
PART 5: RATIONALE FOR APPLICATION	
5.1 Briefly explain the reason for the new investigator/s and/or site(s).	
I, the undersigned, agree to conduct/ manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility to sign this form).	
Applicant (Local Contact): Signature:.....	Date