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

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| This document is intended to be used for application for additional investigator(s) or change of investigator(s) and application for additional sites |

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| Publication released for implementation | v2 CTOBER 2019 |
| Revised released for implementation | v3 March 2020 |

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| 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**

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| Cover Letter (describing the change) one signed in PDF and one in MS-Word format. |
| Two copies of clinical trial application for administrative amendment (CTF3)  (fully completed copies) one PDF and one MS-Word format |
| Investigator documents: SAHPRA format CV, Workload form, Declaration form, GCP  certificate, HPCSA annual registration document, Medical malpractice insurance and  dispensing license (if applicable) |
| 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 |
| Emergency trolley details (for additional site applications) |
| Two Labelled CD-ROM (List of files submitted on CD-ROM) |
| One USB flash drive |
| Any additional information (list them), if applicable |
| Proof of payment |

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

# APPLICATION FOR APPROVAL OF:

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

**ADDITIONAL SITE (S)**

## SECTION 1: ADMINISTRATIVE

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| **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. |  |

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| **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** | |
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| 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). |  |
| 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 |  |
| 3.8 Is the Declaration of Intent attached (list) YES |  |

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| **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). | |
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| **PART 5: RATIONALE FOR APPLICATION** | |
| 5.1 Briefly explain the reason for the new investigator/s and/or site(s). | |
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| 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  ……………………………………. |

# APPENDIX

**Requirements for submission of additional investigator(s) or change of investigator(s) and for**

**additional sites application**

***Note: This Appendix should not be submitted with the application form***

The following are the requirements when submitting amendment application at SAHPRA reception:

1. Cover letter (letter of application), two hard copies

2. Proof of Payment, two hard copies

3. Two Compact Discs (CDs) containing complete additional investigator(s) or change of investigator(s) and additional sites application documents with all the required documents

4. One USB flash drive containing complete additional investigator(s) or change of investigator(s) and

additional sites application documents with all the required documents

**CD-ROM Requirements**

The following statement should be included in the letter of application, after having confirmed that the submission is virus-free:

“We confirm that the CD burning session is closed and the submission is checked with an up-to-date and state-of-the art virus checker: *[name of the antivirus software and version of the virus checker]* and is virus-free". CD (CD-ROM) conforming to ISO 9660 or ISO 13346 can be accepted.

The use of re-writable disks is not encouraged. When using a re-writable disk, all open sessions must be closed before sending the CD. The CD should be packed adequately to prevent damage to the media.

Each CD should include the following label information, clearly presented and printed on the media:

The applicant’s name

The SAHPRA reference number

The Protocol number and version

The data on the CD should not be packed into a zip-file, rar-file or any other file format that has been compressed. One-time security settings or password protection is not acceptable during transportation from the applicant to SAHPRA.

**USB flash drive Requirements**

It should be packaged to include the following label information, clearly presented and printed on the packaging:

The applicant’s name

The Protocol number

The submission date (MM-YYYY)

The data on it should not be packed into a zip-file, rar-file or any other file format that has been compressed.

One-time security settings or password protection is not acceptable during transportation from the applicant to SAHPRA.

**CD and USB flash drive content must contain complete additional investigator(s) or change of investigator(s) and additional sites application documents.**