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| APPLICATION TO CONDUCT A CLINICAL TRIAL Guidance in conditions of a Public Health Emergency |

# \* Application to conduct a clinical trial with limited information

**It is recognized that during a Public Health Emergency, new and experimental treatments may become necessary. Clinical trials are essential to provide the evidence to develop appropriate policies for patient treatments.**

**There may be little information available and a need for regulatory guidance. However, applications need to contain a certain minimum information to enable a meaningful evaluation and regulatory decision. Applicants should attempt to provide the information listed below and justify when this is not available.**

**The required information is GRADED as follows:**

**ESSENTIAL – Application will not be considered without this**

**IMPORTANT – Necessary information that must be provided later – Justify if not available**

**NOT ESSENTIAL – May be omitted from this preliminary application**

**All incomplete information should be explained, justified and provided to CTC as a complete CFT-1, when available. This may mean that repeat evaluations of an application may be necessary.**

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| First Publication released for implementation | V1 April 2020 |

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| **Study title** | Essential to have a working title – but can be updated |
| Protocol No. | Essential to have a working identifier |
| Version No. | Important - Updated with time |
| Study Medicine | Essential – Must be clearly defined.Important: Registration number – approved label (if available) |
| SAHPRA\*Ref. no. (if applicable) | Not essential: Justify if not available |
| SAHPRA\*Ref number(s) of comparator medicine(s) (if applicable) | Not essential: Justify if not available |
| SAHPRA\* Ref number(s) of concomitant medicine(s) (if applicable) | Not essential: Justify if not available |
| Date(s) SAHPRA approval of previous protocol(s) | Not essential |
| Sponsor: | IMPORTANT: Justify if not available |
| Applicant: | Essential Must be defined |
| Contact Person: | Essential: Must be defined |
| Address: | Important: Can be updated |
| Telephone No.: | Essential: Must be defined |
| Fax No.: | Important: Provide when available  |
| Cell No.: | Essential: Must be defined |
| E-mail address: | Essential: Must be defined |
| Date of Application: | Essential: Must be defined |

***\*****Refers to registration number for registered medicines issued by SAHPRA*

## CHECK-LIST

***Refer to the Appendix for instructions – UNSHADED ITEMS ARE ESSENTIAL***

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| [ ]  **Cover Letter - (one signed copy in PDF and one copy in MS-WORD format)** |
| [ ]  **Cover page and fully completed application** |
| [ ]  **Two completed clinical trials application ( CFT1) (one signed copy in PDF and one copy** **in MS-WORD format )** |
| [ ]  **Protocol – [if not finalized, must be close to finalization]** |
| [ ]  **Patient Information Leaflet(s) AND Informed Consent Form(s) – [Draft form]** |
| [ ]  **Copy/ies of Recruitment Advertisement(s) (if applicable) and Questionnaires** |
| [ ]  **Investigators’ Brochure and / or all Professional Information (Package Insert(s))** |
| [ ]  **Certificate(s) of Analysis** |
| **[ ]  Signed Investigator’s CV(s) in SAHPRA format** |
| **[ ]  Signed Declaration(s) by all Investigator(s)** |
| **[ ]  Signed Joint Financial Declaration (Sponsor and National PI) [Justify if not available}** |
| **[ ]  Signed Declaration by Applicant and National Principal Investigator** |
| **[ ]  CV(s) and Signed Declaration by Regional Monitor(s) [Justify if not available}** |
| **[ ]  Proof of Application to Register the Trial on the South African National Clinical Trials Register** |
| **[ ]  Active Insurance Certificate for Clinical Trial [Justify if not available]** |
| **[ ]  Proof of Sponsor Indemnification for Investigators and Trial Site [Justify if not available]** |
| **[ ]  GCP Certificates** |
| **[ ]  Workload Forms for Investigators** |
| **[ ]  Proof of Registration with Professional Statutory Body (HPCSA, SAPC, SANC, etc)** |
| **[ ]  Proof of Professional Indemnity (Malpractice Insurance)** |
| **[ ]  Ethics Approval Letter or Copy of letter submitted to Ethics Committee** |
| **[ ]  Study Budget** |
| **[ ]  Citations** |
| **[ ]  Two Labelled CD-ROM (List of files submitted on CD-ROM)** |
| [ ]  **One USB flash drive** |
| **[ ]  Proof of payment** |

**NB: In an Emergency of public Health importance SAHPRA may accept Research Clinical Trial applications for evaluation with reduced information together with a commitment to update and complete the require information as soon as possible**

**Declaration by Applicant**

I/We, the undersigned have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

I/We, the undersigned will ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements.

Print name

1st Applicant (local contact) Date

Print name

Alternative (local contact) Date

**Declaration by National Principal Investigator**

I, the undersigned as National Principal Investigator agree that I have reviewed the application and protocol and will ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements.

Print name

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National Principal Investigator / Date

Other (state designation)

## SECTION 1: ADMINISTRATIVE

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| **PART 1: ADMINISTRATIVE DETAILS** |
| 1.1 Study Title | Essential: Specify if a Working title - Justify  |
| 1.2 Protocol No, Date and Version | Essential: Specify a working protocol number |
| 1.3 Phase of trial | Not essential |
| 1.4 Sponsor  | Essential - Justify if not available |
| 1.5 Applicant | Essential |
| 1.6 Contact Person (Address, Telephone Number, Fax Number, E-mail Address) | Essential |
| 1.7 National Principal Investigator/Coordinator (or equivalent person) | Essential – All Clinical Trials in South Africa must have a National PI to provide oversight of the entire study |
| 1.8 International Principal Investigator (if applicable) | Not essential |
| 1.9 Regional Monitor | Important: Will be needed before finalization - Justify if not available |

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| **PART 2: DETAILS OF TRIALISTS AND SITES** |
| 2.1 Details of Site(s) (Name of site, physical address, contact details, contact person) | Essential |
| 2.2 Details of how sites were selected | Important |
| 2.3 Details of investigators and staff (Investigators, staff, number of staff, names, qualifications, experience) | Important as much detail as possible; particularly the PI for each site.Please note that each site must have at least one GCP trained PI and one GCP trained Sub-Investigator.Satellite sites may have two Sub-Investigators under supervision of a central PI. |
| 2.4 Details of capacity of site(s): (site facilities, equipment, emergency facilities, other relevant infrastructure and investigator work load documents) | Important: As much detail as is immediately relevant.(E.g. is a -70°C freezer required?) |
| 2.5 Details and evidence of competence of the laboratories:* Collection and processing of samples for shipping to centralised testing facilities (include conditions of shipping)
* Bedside/point-of-contact testing and details of training of staff
* Screening and safety testing of clinical samples during the trial
* Specialised end-point testing (virology, immunology, cytokine analysis)
 | Important:Competent and accredited laboratories should be identified.Certificates etc. can be submitted later. |

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| **PART 3: REGULATORY DETAILS** |
| 3.1 Name other Regulatory Authorities/Ethics Committees to which application to do this trial have been submitted, and/or approved | Important: Justify if not available |
| 3.2 If the trial is to be conducted in SA and not in the host country of the applicant / sponsor, provide an explanation | Not essential - Justify if not available |
| 3.3 Name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection | Essential |
| 3.4 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities | Essential |

## SECTION 2: CLINICAL TRIAL PROTOCOL

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| **PART 4: INVESTIGATIONAL PRODUCT (IP) AND OTHER MEDICINES** |
| 4.1 Details of IP (name, strength, formulation, dose(s), mode of administration and other relevant IP details) | Essential: It is necessary to have a clear description of the IP, and the status of registration/license in other countries (if not registered in SA)Essential: The Dosage form, Presentation, Route of Administration and Strength.A copy of the SAHPRA approved PI should be provided. If this is not available please provide a PI from another accepted Regulatory Authority e.g. EMA, FDA, TGA.  |
| 4.2 Properties of IP i.e. mechanism of action | Important: Description of the relevant properties, supported by suitable reference articles. |
| 4.3 Summary of Pre-clinical findings (e.g. laboratory / animal / toxicity / mutagenicity)  | Essential : Need evidence of acceptable toxicity by the intended route and dose |
| 4.4 Summary of Clinical Findings (e.g. phases; PK; PD; dose-finding; ADRs, NNT/NNH, other).  | Essential: Need evidence from relevant treatments of other conditions by the intended route and dose (if available). |
| 4.5 Details of comparator medicine(s) (name strength, formulation, dose(s), mode of administration and justification of the choice of the comparator) | Essential: Could be an outline to be completed later. |
| 4.6 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required or excluded in the protocol  | Essential: Could be an outline to be completed later - Justify if not available |
| 4.7 Registration status of IP, concomitant and/or comparator medicine(s) (include Investigator’s brochure, SAHPRA approved PI, and other international professional information (package inserts) if not approved in SA and certificate of analysis) | Important: Outline – to be completed later. |
| 4.8 Estimated Quantity of Trial Material (each medicine detailed separately) for which exemption will be required (including overage and justification for overage if above 20%) | Essential: Estimate * Per patient
* Per Site
* For total SA trial population
 |
| 4.9 If any of the above medicines are available in South Africa, give an explanation why they need to be imported from elsewhere  | Not essential |
| 4.10 Details of medicine(s) supply management and accountability (receipt of medicine(s) from supplier, storage, dispensing, packaging and labelling of Investigational Product) | Important: Outline – to be completed later |
| 4.11 Give details of intention to register and justify if registration is not envisaged | Not essential |
| 4.12 Details of the manufacture, quality control and stability of the IP | Essential: Outline of processes, GMP manufacture and Control for new medicinesOr Evidence of registration by SAHPRA or another Regulatory Authority |
| 4.13 Previous studies using this medicine which have been approved by SAHPRA\* and include SAHPRA\* approval number Study title, Protocol number, Date of approval, National PI / Principal Investigator, Date(s) Progress report(s) and Date Final report) | Not essentialMay not be essential but could be helpful.To be completed later |

\**This include all studies approved in the previous SAHPRA dispensation called Medicines Control Council*

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| **PART 5: BACKGROUND INFORMATION** |
| 5.1 Disease / problem in South African context (e.g. local epidemiology)  | Important: Brief summary |
| 5.2 Overall rationale for the study summarised | Essential  |
| 5.3 Rationale for the study in the South African context | Essential |

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| **PART 6: STUDY OBJECTIVES AND ENDPOINTS** (with justifications) |
| 6.1 Primary objectives and endpoints | Essential: Need a clear description with matching endpoint tests that will provide answers of the required specificity and sensitivity |
| 6.2 Secondary objectives and endpoints | Essential: Need a clear description with matching endpoint tests that will provide answers of the required specificity and sensitivity |
| 6.3 Exploratory objectives and endpoints | Not essentialNeed a clear description with matching endpoint tests that will provide answers of the required specificity and sensitivity |
| 6.4 Safety objectives and endpoints | Essential: SAFETY is ALWAYS a Primary objective |
| 6.5 Other objectives |  |

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| **PART 7: STUDY DESIGN AND METHODOLOGY** |
| 7.1 Study Design (with justifications) * phase of trial
* choice of design
* use of placebo (if applicable)
* dosages
* randomisation
* blinding
 | Essential: Need a clear description including justification for placebo or lack thereof. |
| 7.2 Duration of the study | Important: Estimated time |
| 7.3 Planned start and stop date of the study  | Important: Estimated dates |
| 7.4 Participant numbers (local and worldwide) include participant numbers per site in South Africa | Important: Estimates – Justify any possible adaptive designs |
| 7.5 Provide information indicating potential of each site to recruit required number of patients within envisaged duration of trial | Important: Outline is acceptable |
| 7.6 Provide details of pharmacogenetic, biobanking or other sub-studies planned | Essential: Outline – Details can be provided later |

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| **PART 8: ELIGIBILITY CRITERIA** (with justification for each criterion) |
| 8.1 Inclusion criteria | Essential: In as much detail as possible – Justify any uncertainties |
| 8.2 Exclusion criteria | Essential: In as much detail as possible |

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| **PART 9: DATA AND SAFETY MONITORING PLAN** |
| 9.1 Describe and comment on Data and Safety monitoring plan (provide detailed safety and monitoring plan for the study and explain how adequate site oversight will be ensured) | Essential: Need commitment to provide:Monitor for Site Audits with SOPsSafety monitoring groupIndependent Data and Safety Monitoring Board (DSMB) |
| 9.2 Provide details of Composition, Charter and Stopping rules of the Data Safety Monitoring Committee if applicable | Essential: Commitment to provide a DSMB – if appropriate |
| 9.3 Provide details of interim analyses if planned | Important: Outline  |
| 9.4 Provide AE and SAEs definitions, reporting guidelines and causality assessments to be followed Provide details of AE’s and SAEs of special interest  | Important: Refer to SAGCPCommit to report SAEs to SAHPRA as required. |

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| **PART 10: STATISTICAL MEASURES** |
| 10.1 Provide method of Sample size determination (justification of the power of the study in relation to the outcomes measures) | Essential: Outline of the statistical plan,Consideration of participant numbers and calculated power of the study to meet objectives. |
| 10.2 Provide Statistical method(s) and analysis of qualitative and/or quantitative measures with appropriate, clear justification | Important: May be provided later if there is an Adaptive Design. |
| 10.3 Details of data processing * how
* where
* when
* who
 | Important: May be provided later. |

| **PART11: ETHICAL AND ADMINISTRATIVE ISSUES** |
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| 11.1 Justification for deviation from current SA GCP guidelines  | Not essential: Can be provided later |
| 11.2 Provide details of capacity building and transformation at all sites | Not essential |
| 11.3 Provide details of insurance (including title, protocol, dates, policy #, amount, local vendor) | Essential: Outline of intended insurance cover.Evidence will be required before approval |
| 11.4 Provide details of indemnity for Investigators and trial site  | Essential: Evidence will be required before approval |
| 11.5 Ensure Patient Information Leaflet and Informed Consent / Assent includes:* latest ABPI and SA GCP guidelines
* written in appropriate level of education/English
* explains possible benefits / risks
* ensuring patient rights
* SAHPRA and Ethics contact names and numbers
* Other details as per ICH GCP
* Confirm translations available
 | Essential: Outline is required. |
| 11.6 Provide separate PILs and informed consent forms for any proposed * archiving of blood specimens for later research
* genetics research
* HIV testing
* any other
 | Essential: Outline is required |
| 11.7 Provide details of publication policy | Not essential |
| 11.8 Provide details of remuneration and other benefits for participants  | Important: Outline is required with justification |
| 11.9 Provide details of remuneration of investigators or site | Important: Outline is required |
| 11.10 Provide a list of Ethics Committees which will be involved in approving the study  | Essential |
| 11.11 Provide details of possible conflict of interest of any person(s)/organisation(s) who/which will be involved in the trial | Important: Completed Declaration forms from investigators |
| 11.12 Provide updated proof of GCP training for staff involved in this trial (done in the past three years) | ImportantMust be complete before trial approval |
| 11.13 Provide details on treatment and/or management of participants and their disease condition(s) after completion of trial (Post trial medicine access) | Important: Outline – if relevant |

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| **PART 12: ADDITIONAL COMMENTS** |
| Provide any additional information that may be relevant to the study | Important: Outline of international collaborations if relevant |

## Annexure 1

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| **STANDARDISED WORDING TO BE ADDED TO PARTICIPANT INFORMATION LEAFLET (PILs)**If you have questions about this trial, you should first discuss them with your doctor or the Ethics Committee (contact details as provided on this form). After you have consulted your doctor or the Ethics Committee and if they have not provided you with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA) at:The Chief Executive OfficerSouth African Health Products Regulatory Authority Department of HealthPrivate Bag X828PRETORIA0001E-mail: Boitumelo.Semete@sahpra.org.zaTel: 012 842 7629/7626 |

## Annexure 2

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| SAHPRA FORMAT FOR CVs OF INDIVIDUALS PARTICIPATING IN THE CONDUCT OF CLINICAL TRIALS IN SOUTH AFRICA |
| 1. Trial:2. Protocol:3. Designation: (e.g. National Principal Investigator, Investigator (Principal, Co-Principal or sub-I), Study Co-ordinator, Regional Monitor, Local Monitor, Contract Research Affiliate) |
| 4. Personal DetailsName:Work Address:Telephone Number:Fax Number:Cell-phone Number:e-mail address: |
| 5. Academic and Professional Qualifications |
| 6. Professional Statutory body registration number i.e. HPCSA, SAPC, SANC, etc.  |
| 7. Current personal medical malpractice insurance details (all investigators) |
| 8. Relevant related work experience (brief) and current position |
| 9. Participation in clinical trials research in the last three years (title, protocol number, designation) [If multiple trials, only list those with relevance to this application, or in the last years.] |
| 10. Peer-reviewed publications in the past 3 years |
| 11. Date of last GCP training (as a participant or presenter) |
| 12. Any additional relevant information supporting abilities to participate in conducting this trial. [briefly] |
| 13. Signature: Date: |

## Annexure 3

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| **DECLARATION BY PRINCIPAL OR CO-PRINCIPAL INVESTIGATOR** |
| **Name:****Title of Trial:** **Protocol:** **Site:** |
| 1. I have read and understood ‘Responsibility of The Principal Investigator (PI) and Participating Investigators’ of the current Good Clinical Practice Guidelines of the Department of Health.
2. I have notified the South African Health Products Regulatory Authority (SAHPRA) of any aspects of the above guidelines with which I do not / am unable to, comply. (If applicable, this may be attached to this declaration.)
3. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol and all applicable accompanying documentation, including the investigator’s brochure, patient information leaflet(s) and informed consent form(s).
4. I will conduct the trial as specified in the protocol.
5. To the best of my knowledge, I have the potential at the site(s) I am responsible for, to recruit the required number of suitable participants within the stipulated time period.
6. I will not commence with the trial before written authorisations from the relevant ethics committee(s) as well as the SAHPRA have been obtained.
7. I will obtain informed consent from all participants or if they are not legally competent, from their legal representatives.
8. I will ensure that every participant (or other involved persons, such as relatives), shall at all times be treated in a dignified manner and with respect.
9. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial.

*[Conflict of interest exists when an investigator (or the investigator’s institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions.]\**\*Modified from: Davidoff F, *et al.* Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 1. I have\* / have not (delete as applicable) previously been the principal investigator at a site which has been closed due to failure to comply with Good Clinical Practice. (\*Attach details.)
2. I have\* / have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices. (\*Attach details)
3. I will submit all required reports within the stipulated time-frames.
 |
| Signature: Date: |
| Witness: Date: |

## Annexure 4

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| **JOINT DECLARATION BY SPONSOR (OR REPRESENTATIVE) AND PRINCIPAL INVESTIGATOR (OR NATIONAL PRINCIPAL INVESTIGATOR) CONCERNING SUFFICIENT FUNDS TO COMPLETE STUDY\*** |
| Title: |
| Protocol: |
| I, <full name>, representing <sponsor or representative)AndI, <full name>, Principal Investigator/National Principal InvestigatorHereby declare that sufficient funds have been made available to complete the above-identified study. |
| Signed: Date: |
| SPONSOR (or alternative)Name: Address:Contact details: |
| Signed: Date: |
| PRINCIPAL INVESTIGATOR (or National PI)Name:Address:Contact details: |
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## Annexure 5

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| **PROVISIONAL DECLARATION BY SUB-INVESTIGATORS AND OTHER STAFF INVOLVED IN A CLINICAL TRIAL** |
| Name:Title of Trial: Protocol: Principal Investigator’s Name:Site:Designation:  |
| 1. I will carry out my role in the trial as specified in the protocol. 2. I will not commence with my role in the trial before written authorisations from the relevant ethics committee(s) as well as the South African Health Products Regulatory Authority (SAHPRA) have been obtained.3. If applicable to my role in the trial, I will ensure that informed consent has been obtained from all participants or if they are not legally competent, from their legal representatives. 4. I will ensure that every participant (or other involved persons, such as relatives), shall at all times be treated in a dignified manner and with respect. 5. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. *[Conflict of interest exists when an investigator (or the investigator’s institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions.]\**\*Modified from: Davidoff F, *et al.* Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 6. I have\* / have not *(delete as applicable)* previously been involved in a trial which has been closed due to failure to comply with Good Clinical Practice. *(\*Attach details)*7. I will submit all required reports within the stipulated time-frames. |
| Signature: Date:  |
| Witness: Date: |

## Annexure 6

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| **DECLARATION BY REGIONAL MONITOR** |
| Name:Title of Trial: Protocol: Principal Investigator’s Name:Site:Designation:  |
| 1. I have read and understood “The Monitor” of the current Clinical Trials Guidelines of the Department of Health.
2. I have notified the South African Health Products Regulatory Authority of any aspects of the above guidelines with which I do not / am unable to, comply. *(If applicable, this may be attached to this declaration.)*
3. I will carry out my responsibilities as specified in the trial protocol and according to the current Good Clinical Practice Guidelines of the Department of Health.
4. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial.

[*Conflict of interest exists when an investigator (or the investigator’s institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions*.]\*\*Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 1. I have\* / have not *(delete as applicable)* previously been the monitor at a site which has been closed due to failure to comply with Good Clinical Practice. *(\*Attach details.)*
2. I have\* / have not *(delete as applicable)* previously been involved in a trial which has been closed as a result of unethical practices. *(\*Attach details)*
3. I will submit all required reports within the stipulated time-frames.
 |
| Signature: Date:  |
| Witness: Date: |

## Annexure 7

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| **WORDING FOR THE SPONSOR INDEMNIFICATION FOR SITES AND INVESTIGATORS** In consideration of the {PI’s / Institution’s / Research Unit’s] participation in the study, we shall indemnify and hold harmless [Name of PI / Institution / Research Unit] and its employees from any legal liability for costs or damages for death or personal injury which may result from the administration of [Name of compound] pursuant to the said study. This indemnity does not apply to the extent that such death or personal injury arises out of any negligent act, default or omission of [Name of PI / Institution / Research Unit] or its employees. Furthermore, this indemnity is subject to the condition that the study is carried out in accordance with the Protocol approved by us in writing, that [Name of Sponsor] is notified immediately on receipt of any claim, that [Name of Sponsor] shall have full control of the management and defence of any such claim and that no offer to compromise or settle any claim is made without the written agreement of [Name of Sponsor]. |

Note: The wording for Sponsor Indemnification for investigators and sites serves as a guide and is not an exclusive approach.

## Annexure 8

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| **WORKLOAD TABLE** |
| Date  |  |
| Study Title |  |
| Protocol number  |  |
| Phase of study |  |
| Investigator (Title, Name and Designation i.e. PI, Co-PI or sub-I) |  |
| Primary Employer *e.g* University, Research Unit, CRO, Private Practice of the investigator |  |
| Area of expertise of Investigator |  |
| Area of Study Research (*e.g*. oncology, cardiology) |  |
| **NUMBER OF CURRENT CLINICAL TRIALS OF INVESTIGATOR’S INVOLVEMENT** |
| **Role (Principal Investigator/Co-PI or Sub-Investigator)** | **Number of participants responsible for in actively recruiting clinical trials**  | **Number of participants responsible for in follow-up clinical trials**  | **Number of actively recruiting clinical trials**  | **Number of clinical trials in follow-up clinical trials** |
| Principal /Co-Principal Investigator |  |  |  |  |
| Sub-Investigator |   |  |  |  |
| **ESTIMATED TIME PER WEEK**  | Hours |
| Clinical trials | Clinical work (patient contact) |  |
| Administrative work |  |
| Organisation 1 (e.g. Private practice / University / Governmental) | Clinical / Routine work |  |
| Teaching/Research  |  |
| Administrative work |  |
| Organisation 2 (e.g. Private practice / University / Governmental), if applicable | Clinical / Routine work |  |
| Teaching / Research |  |
| Administrative work |  |
| Organisation 3 (e.g. Private practice / University / Governmental), if applicable  | Clinical / Routine work |  |
| Teaching / Research |  |
| Administrative work |  |
| Total  |  |  |
| **Investigator Signature:** | **Date:**  |

## APPENDIX

**Requirements for submission of a clinical trial application**

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

The following are the requirements when submitting a clinical trial 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 Clinical Trial Application documents with all the required documents

4. One USB flash drive containing complete Clinical Trial 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 Protocol number
* The submission date (MM-YYYY)

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 Clinical Trial Application documents.**

1. Cover letter (one signed in PDF and one in MS-Word format)
2. Two completed copies of the clinical trials application (CTF1) one signed in PDF and one in MS-Word format
3. Checklist

4. Protocol

5. Patient Information leaflets and Informed consent forms (PIL/ICF). Include a standardised South African Health Products Regulatory Authority (SAHPRA) contact details in PIL/ICON **(Annexure 1)**

6. Relevant questionnaires

7. Investigators Brochure / SAHPRA and other regulatory authorities’ approved professional information (Package insert(s))

8. Certificate of analysis of the product

9. Signed investigator(s) Curriculum Vitae(s) (CV) in SAHPRA format **(Annexure 2)**

10. Signed declaration by Co- or Principal investigator(s) **(Annexure 3)**

11. Signed joint declaration by Sponsor/National Principal investigator **(Annexure 4)**

12. Signed declaration by Applicant

13. Signed declaration by National Principal Investigator **(See page 4 and Annexure 3)**

14. Signed declaration by Sub-investigators **(Annexure 5)**

15. Curriculum Vitae(s) (CV) and signed declaration by regional monitor **(Annexure 2 and Annexure 6)**

16. Proof of application to register the trial on the South African National Clinical Trials Register

17. Active Insurance Certificate for clinical Trial

18. Proof of Sponsor Indemnity for Investigators and trial site(s) **(Annexure 7)**

19. GCP Certificates (not more than 3 years old)

20. Workload forms for investigators **(Annexure 8)**

21. Proof of registration with professional statutory bodies

22. Proof of professional indemnity (Malpractice insurance) of trialist(s)

23. Ethics Committee(s) approval letter or Copy of letter submitted to Ethics committee(s).

24. Study Budget

25. Citations

26. Proof of payment

**Note: The application and all supporting documents should also be emailed to the central email address:** **ctcresponses@sahpra.org.za**