|  |
| --- |
| **DECLARATION BY PRINCIPAL INVESTIGATOR AND SUB-INVESTIGATOR** |

Name:

Trial:

Brief Study Title:

Study Number:

Site:

1. I have read and understood item 1.5.5 on page 5 and section 3 (pages 14-20) “Responsibility of the Principal Investigator (PI) and participating investigators of the *Clinical Trials Guidelines of the Department of Health: 2000*
2. I have notified the South African regulatory authority of any aspects of the above guidelines with which I do not / 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 forms(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 my role in the trial before written authorizations from the relevant ethics

 committee (s) as well as the South African Medicines Control Council (MCC) 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 orher actions)\**

 \*Modified from: Davidhoff F, et al. Sponsorship, Authorship and Accountability.

 (Editorial) JAMA Volume 286 number 10 (September 12, 2001)

10. 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.

11. 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 Practise (\*Attach details)

12. I will submit all required reports within the stipulated time-frames.

 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

 Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_