

**PVF 80** 

## PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

<u>_</u>	DECLARATION BY PRINCIPAL INVESTIGATOR FOR GCP COMPLIANCE	
Name: Title of Trial:		
Site: _		
1.	I am familiar with internationally accepted standards of Good Clinical Practice (GCP) and understand the responsibilities and obligations of the Principal Investigator within the context of this study.	
2.	I have notified the MCAZ of any aspects of the above 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 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 and in accordance with Good Clinical Practice (GCP).
- 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 Research Ethics Committee(s) as well as the MCAZ 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), 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 associations with other persons or organizations that may 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)
- 10. 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.)
- 11. 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)
- 12. I will submit all required reports within the stipulated time-frames.

Signature:	Date:
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Witness:	Date: