Medicines Control Authority of Zimbabwe

PVF 81

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

DECLARATION BY CO- AND SUB-INVESTIGATORS FOR GCP COMPLIANCE

Name: _____

Title of Trial:

_____

_____

_____

Principal Investigator's Name: _____

Site: _____

Designation: _____

1. I am familiar with internationally accepted standards of Good Clinical Practice (GCP) and understand the responsibilities and obligations of the Investigator within the context of this study.
2. I will carry out my role in the trial as specified in the protocol and in accordance with Good Clinical Practice (GCP).
3. I will not commence with my role in the trial before written authorisations from the relevant Research Ethics Committee(s) as well as the MCAZ have been obtained.
4. 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.
5. 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.
6. 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)*
7. I have not previously been involved in a trial which has been closed due to failure to comply with Good Clinical Practice.
8. I will submit all required reports within the stipulated time-frames.

Signature: _____ Date: _____

Witness: _____ Date: _____