Quality Medicines for Malawi

FORMAT FOR DECLARATIONS BY INVESTIGATORS

Trial Protocol Number. ……

Name: Role in Trial……..

Clinical Trial Title:……..

Site: A current Curriculum Vitae is attached.

1 I am aware of the responsibilities of my role as . . . . in clinical trial number . . . . . as required by the legal, ethical and regulatory requirements of Malawi

2 I have read and understand the attached Protocol, Investigators Brochure and supporting documentation and I will comply with the procedures and requirements included in them.

3 I have read the attached Clinical Trial Application form as submitted to the regulatory authority in Malawi and confirm that the information is complete, true and accurate, and conforms to the Protocol and supporting documentation.

4 I will not commence with this trial before written authorization has been received from the Pharmacy and Medicines Regulatory Authority and the relevant Ethics Committee/s. I will provide the IEC and PMRA with reports as required.

5 I will obtain Informed consent from all participants, or if they are not legally competent, from their legal representatives, parents or guardian.
I will ensure that every participant (and other involved person, such as relatives) will be treated in a dignified manner and with respect.

6 I DECLARE: I have no conflict of interest in terms of financial interests or personal relationships that may inappropriately influence my responsibilities and conduct of this trial.

Initials: . . . . . .

7 I DECLARE: I have not previously been associated with any clinical study that has been terminated, or study-site that was closed, due to failure to comply with Good Clinical Practice.

Initials: . . . . . .

8 I have the malpractice insurance, that will provide cover for my activities in this clinical trial, as required in Malawi
Malpractice Insurance Number . . . . . ……..

9 I have received suitable, recent training in Good Clinical Practice in Malawi context (attached)

10 SIGNED . . . . DATE . . . . . ……

WITNESS NAME: . . . . . SIGNATURE…. . . . . DATE . . . . . ……..