**MINISTRY OF HEALTH**

# PHARMACY AND POISONS BOARD

## Declaration by Applicant

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

We, the undersigned, agree that;

1. It is reasonable for the proposed clinical trial to be undertaken;
2. We will ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and Kenyan legal, ethical, PPB requirements and principles of Good Clinical Practice
3. We will ensure the safety, well being of participants and also act to ensure the integrity of the data generated
4. We will submit reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) and safety reports according to applicable guidance
5. We will submit a summary of the final study report to the PPB and the ethics committee concerned within a maximum 6 months deadline after the end of the study in all countries.

_____ _____

Name, Position and Contact details (Local contact) Date

_____ _____

Name and Contact details
Principal Investigator /
National Co-ordinating PI Date