



## DECLARATION AND WORKLOAD OF PRINCIPAL INVESTIGATOR

MCA-F-501/02

<b>Name of PI:</b>	
<b>Site:</b>	
<b>Title of the trial:</b>	
<b>Protocol No:</b>	
<b>Date of application</b>	

1. I have read and understood the duties and responsibilities of the principal investigator as outlined in the guideline for good clinical practice (ICH-GCP) as last amended
2. I have notified the Medicines Control Agency The Gambia of any aspects of the above guideline with which I do not / am unable to comply and attached it to this declaration, if applicable
3. I have thoroughly read, understood, and critically analysed the protocol and all applicable documentation, including the investigator's brochure or summary of product characteristics or equivalent, as applicable and the informed consent documentation
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 the trial before the relevant ethics committee(s) and the Medicines Control Agency The Gambia provide written authorisation
7. I will obtain informed consent from all participants or from their legal guardian/representative if they are not legally competent
8. I will ensure that every participant shall at all times be treated in a dignified manner and with respect including relatives
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 during the conduct of this clinical trial  
*Conflict of interest exists when an investigator or the investigator's institution has financial or personal relationships with other persons or organisations that inappropriately influence (bias) his or her actions.*
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 (details attached if applicable)
11. I have / have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices (details attached if applicable)
12. I will submit all required reports within the stipulated timeframes

**Current workload of the principal investigator at time of application**

Total number of clinical trials currently undertaken by the principal investigator		
Dates of commencement:	1	
	2	
	3	
	4	
Expected dates of completion of study	1	
	2	
	3	
	4	
Total number of clinical research projects currently undertaken by the principal investigator in addition to the clinical trials		
Total number of patients or participants for which the principal investigator is responsible		

Other responsibilities of the principal investigator during the anticipated duration of the clinical trial applied for <i>Estimated hours per month</i>	Yes	No	Hours
Clinical service / Patient care			
Teaching			
Writing Publications			
Presentation at conferences/meetings/etc			
Administrative work			
Other (specify)			

.....  
Signature of principal investigator

.....  
Date