

DECLARATION BY PI OR CO-PI

Note that all investigators should fill and sign this form

Title of clinical trial:	
Role in clinical trial:	
Title of clinical trial:	
Clinical trial protocol number:	
Investigational Product:	
Clinical trial site:	

DECLARATION

I, *(Insert Full names)*, the **principal investigator or co-investigator** *(delete as applicable)* in above mentioned study, hereby DECLARE that:

1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and understand the responsibilities and obligations of the Principle Investigator (PI) within the context of this study.
2. I have notified the Rwanda FDA of any aspects of the study 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 analyzed 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 Rwanda FDA requirements and ICH – GCP principles.
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.
6. I will not commence the trial before written authorization from the National Ethics Committee and Rwanda FDA has 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*].

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 ICH-GCP (*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).

Principal Investigator:	Date	Signature