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| *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** |
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