**INFORMED CONSENT FORM(ICF)**

**Title: [***Insert the Project Title***]**

**Short Title: [***Short Project Title if Any***]**

**Protocol Number: [*Insert the Protocol Number*]**

**Project Sponsor: [*Insert the names of Project Sponsor*]**

**Principal Investigator: [***Insert the names of Principal Investigator***/**

**Research Site: [*Location where the research will be conducted*]**

I [*insert the names of participant*] have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received**.**

I understand that research team, representatives from the sponsor, members of the National Ethics Committee or Rwanda FDA overseeing this study and will be given access to my medical records so they can verify what was done and look at the data. In signing this, I authorize access to my medical records.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without penalty and any loss of medical care

I understand that I will be given a signed copy of this document to keep.

I voluntarily agree to participate in this study.

***[Insert the Names of Participant (please print)]***

**Signature Date:** (DD/MM/YYYY)

**Declaration by Researcher**

I have given a verbal explanation of the research project [ Insert the name of research]; its procedures and risks and I believe that the participant has understood that explanation.

***[Insert the Names of Participant (please print)]***

**Signature Date:** (DD/MM/YYYY)

**Title: [***Insert the Project Title***]**

**Short Title: [***Short Project Title if Any***]**

**Protocol Number: [*Insert the Protocol Number*]**

**Project Sponsor: [*Insert the names of Project Sponsor*]**

**Principal Investigator: [***Insert the names of Principal Investigator***/**

**Research Site: [*Location where the research will be conducted*]**

I [*insert the names of participant*] have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I have read the patient information sheet, or it has been read to me, and I have understood the purpose of the study, the procedure to be conducted, and the risks and benefits related to my participation. I have had the opportunity to ask questions and all have been answered to my satisfaction.

I understand that study staff, representatives from the sponsor, members of the ethics committee overseeing this study and the regulatory authority will be given access to my medical records so they can verify what was done and look at the data. In signing this, I authorize access to my medical records.

I understand that I may drop out of this study at any time, for any reason, without penalty and without any loss of medical care.

I voluntarily agree to participate in this study.

***[Insert the Names of Participant (please print)]***

**Signature Date:** (DD/MM/YYYY)

**Witness (if participant is illiterate):**

I have witnessed the accurate reading of the consent form to the participant. I confirm that the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

***[Insert the Witness Names of Participant (please print)]***

**Signature Date:** (DD/MM/YYYY)

**INFORMED CONSENT FORM(ICF) FOR LITERATE PARENT**

**Title: [***Insert the Project Title***]**

**Short Title: [***Short Project Title if Any***]**

**Protocol Number: [*Insert the Protocol Number*]**

**Project Sponsor: [*Insert the names of Project Sponsor*]**

**Principal Investigator: [***Insert the names of Principal Investigator***/**

**Research Site: [*Location where the research will be conducted*]**

**Declaration by literate parents or guardians of participants aged 5 to 17years (children)**

I [*insert the names of participant*] have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I have read the patient information sheet, or it has been read to me, and I have understood the purpose of the study, the procedure to be conducted, and the risks and benefits related to my child’s participation. I have had the opportunity to ask questions and all have been answered to my satisfaction.

I understand that study staff, representatives from the sponsor, members of the ethics committee overseeing this study and the regulatory authority will be given access to my child’s medical records so they can verify what was done and look at the data. In signing this, I authorize access to my child’s medical records.

I understand that my child may drop out of this study at any time, for any reason, without penalty and without any loss of medical care.

I voluntarily agree for my child to participate in this study.

***[Insert the Names of Child Participant*** ***(please print)]***

**Signature Date:** (DD/MM/YYYY)

***[Insert the Names of Witness Parent/Legal Guadian*** ***(please print)]***

Relationship with the participant: Mother /Father /Other legal guardian, specify……………

**Signature Date:** (DD/MM/YYYY)

**INFORMED CONSENT FORM(ICF) FOR CHILDREN**

**Title: [***Insert the Project Title***]**

**Short Title: [***Short Project Title if Any***]**

**Protocol Number: [*Insert the Protocol Number*]**

**Project Sponsor: [*Insert the names of Project Sponsor*]**

**Principal Investigator: [***Insert the names of Principal Investigator***/**

**Research Site: [*Location where the research will be conducted*]**

**For witnesses of illiterate parents or guardians of participants aged 5 to 17years (children)**

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Consenting parents/guardians who are illiterate should include their thumb print.

I have witnessed the accurate reading of the consent form to the parent/guardian of the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

***[Insert the Names of Child literate Participant*** ***(please print)]***

**Signature Date:** (DD/MM/YYYY)

***[Insert the Names of Witness Parent/Legal Guadian*** ***(please print)]***

Relationship with the participant: Mother/ Father /Mother/ Father /Another legal guardian, specify: …

**Signature Date:** (DD/MM/YYYY)

**Investigator (or designee):**

I, the undersigned, have defined and explained to the participant in a language he/she understands, the procedures of this study, its aims and the risks and benefits associated with his/her participation. I have informed the participant that confidentiality will be preserved, that he/she is free to withdraw from the trial without affecting the care he/she will receive at the hospital. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

***[Insert the Names of Investigator/Designee*** ***(please print)]***

**Signature Date:** (DD/MM/YYYY)