**Study Title:**

**Study Centre:**

**Principal Investigator:**

**Sponsor**:

**Language:** English/French/Kinyarwanda

**INTRODUCTION**.

* 1. **What does my participation involve?**

*The purpose of this section is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the form and the nature of informed consent.*

**Examples of statement:**

You are invited to take part in this research project, which is called [*Name of research project*]. You have been invited because [*Explain reason for invitation*]. Your contact details were obtained by/from [*provide details].*

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

* Understand what you have read
* Consent to take part in the research project
* Consent to be involved in the research described
* Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep. You will be given a copy of this Participant Information Sheet to keep.

* 1. **What is the purpose of this research?**

Briefly describe the following aspects of your project in simple terms and in only a couple of sentences for each point:

* Aim of the project and its significance
* How the project is intended to fill any gap in knowledge
* How it may contribute to care or education or research in the future
* Any relevant background including what is already known
* Whether the research is for the purpose of obtaining a degree or other educational qualification, is funded by a grant, or has sponsorship of some kind.
  1. **What does participation in this research involve?**

*Include information and clear explanation of the following:*

* *Consent form will be signed prior to any study assessments being performed*
* *Initial steps: Screening for eligibility, Randomisation and/or the use of a control group Where a control group or similar methodology is to be used in your research, you should include a statement that participants may be allocated to either a control or experimental group, and that they may not be told which of these groups they are in.*
* *Procedures and Activities: all procedures and activities, nature, number, timing and time commitment of procedures and activities, visits, questionnaires, interviews, focus groups, etc:*

1. *Nature of follow-up*
2. *Duration of participant’s involvement (including follow-up)*
3. *Duration of the research project (if this is different from their involvement)*

* *Reimbursement and costs (if applicable)*
* *How the research will be monitored*
* *The commitment required by the participant*
* *Access to personal records that may be required*
* *Whether any part of the research project will be recorded (video/audio). Information that should be included: They will be taped or photographed (they should also be reminded of this before data is collected).*

*The tape or a certified transcript of the tape is raw data and will be securely retained for five years.*

*Their identity can be masked if they request this.*

*If another organisation or person has rights of access to the data collected on tape.*

* *Details on the use of interpreters in the consent and/or data collection process*
* *Venue details and a statement whether participants may choose the venue*

*Explain any other relevant information including:*

* *How many people will be taking part in the project overall and at this site*
* *Whether there are different groups e.g. case/control groups, different types of focus groups*
* *The size or scope of a project e.g. number of schools or hospitals or countries involved*
* *Whether the project involves researchers from a number of organizations working in collaboration*
* *Whether this is a follow-on study/sub-study/extension study. If so, state the relationship to the previous research and specify if data may be used for future research*

*Email or internet distribution*

*If you will use email or the internet to distribute questionnaires and receive responses, you should include the following statement in the information provided to participants:*

*The researcher will take every care to remove any identifying material from the responses you provide as early as possible. Likewise, individuals' responses will be kept confidential by the researcher and will (or participants will) not be identified in the reporting of the research. However, the researcher cannot guarantee the confidentiality or anonymity of material transferred by email or the internet.*

**Examples of statement:**

If you decide to take part in the research project, you will first be given a questionnaire asking about [*provide details];* this will determine if you are eligible to take part. Completing the questionnaire will take approximately [*specify expected time*].

If the screening questionnaire shows that you meet the requirements, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, the research coordinator will discuss other options with you.

This research project has been designed to make sure the researchers interpret the results in a fair a There are no costs associated with participating in this research project, nor will you be paid.

However, you may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit and appropriate way and avoids study doctors or participants jumping to conclusions.

* 1. **Other relevant information about the research project?**

*Explain any other relevant information including:*

* + - * *How many people will be taking part in the project overall and at this site*
      * *Whether there are different groups e.g. case/control groups, different types of focus groups*
      * *The size or scope of a project e.g. number of schools or hospitals or countries involved*
      * *Whether the project involves researchers from a number of organisations working in collaboration*
      * *Whether this is a follow-on study/sub-study/extension study. If so, state the relationship to the previous research*
  1. **Information of Investigational Products**

*In addition to the usual information, participant information sheets for protocols involving drug therapy must include:*

* *Name of drug (generic preferred, trade name if necessary to the study design)*
* *any conditions in which the drug should not be taken (for example during pregnancy)*
* *whether the drug is meant to treat the disease or to relieve symptoms, and therefore how important it is to take the drug*
* *how to tell if the drug is working and what to do if it appears not to be working*
* *when and how to take the drug (for example before or after meals)*
* *what to do if a dose is missed and the implications of not taking the drug for any length of time*
* *any interactions with alcohol or other drugs (generic and trade names)*
* *storage and disposal of the drug*
* *risks, side effects, discomforts, inconveniences, restrictions, or other negative effects which might occur as a result of taking the drug*
* *the probability of adverse effects from the test drug compared with other procedures (or drugs) used for the same purpose*
* *any category of participant to be excluded from the research*
* *an explanation that randomisation and/or placebos may be used (where relevant)*
  1. **Radiation**

*In addition to the usual information, participant information sheets for protocols involving radiation must include the following statement*

*In this project you will be exposed to radiation at a level considered safe for you as long as you have not also been exposed to radiation in other research projects or as a part of investigation (X-Rays) or treatment (Radiotherapy) in the past year. Please advise the researcher if you have had any exposure to radiation for any reason in the last year.*

* 1. **Do I have to take part in this research project?**

*Explain that taking part in the research is entirely voluntary.*

**Examples of statement:**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with [*Institution*].

* 1. **What are the possible benefits of taking part?**

*Do not attempt to build up participant hope in this section. Reference to the potential benefit to others in the future may be appropriate, but should not be exaggerated. You should give potential participants an idea of what they should expect if they agree to take part. It is important that you consider their perspective and likely view of any impacts on them, their lives and those close to them. Potential participants need to know what they are being asked to give consent to, so make it clear what elements are additional to standard care, and/or what elements of standard care they may not receive if they agree to take part.* *There will be specific issues pertinent to your particular study and the types of participants you intend to recruit which must be considered here (e.g. adults not able to consent for themselves or children / young people). Specific issues may include:*

**Examples of statement:**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include [*describe any likely benefits to participants or other people in the future*].

* 1. **What are the possible risks and disadvantages of taking part?**

*Provide information on the possible risks with taking part in this research project and strategies the researchers will use to manage and/or minimize the risks. Please include details of all significant risks of harm, risks to confidentiality and psychological risk. Some specific issues you should consider include:*

* *Impact on possible pregnancy and breast feeding, including young people and pregnancy*
* *Side effects of treatments / therapies in trials*
* *Discovering health related findings*
* *Impact on insurance*

*Try to describe the likelihood of adverse things happening, as well as severity in language all potential participants are likely to understand All group participants will be asked to maintain the confidentiality of group discussions and identity of participants.*

*Finally, you should provide potential participants with more details of what is involved so that you can fully support them in making an appropriate decision. Some of the issues that might be appropriate here include:*

* *What if something goes wrong?*
* *What will happen if I don't want to carry on with the study?*
* *How will my information be kept confidential?*
* *What will happen to the results of this study?*
* *Who is organizing and funding this study?*
* *How have patients and the public been involved in this study?*
* *Who has reviewed this study?*
* *Further information and contact details*
* *What to expect during the consent process?*
* *What if relevant new information becomes available?*
* *Informing General Practitioner / other healthcare practitioner*
* *What will happen to the samples I give?*

**Examples of statement:**

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge

* 1. **What if I withdraw from this research project?**

*Provide information regarding how participants withdraw and implication for them if they do so. Include information on the use and submission of the withdrawal of consent form. Where appropriate, explain that if a participant withdraws part-way through a research project that data collected to that point may not be able to be deleted.*

**Examples of statement**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

* 1. **Could this research project be stopped unexpectedly?**

*The participant should be advised of the potential for the project to be terminated before completion and the reasons that might make termination necessary.*

**Examples of statement**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as [*provide details of possible reasons*].

* 1. **What will happen to information about me?**

*Information should be provided regarding the following:*

* *Whether the data collected or used is individually identifiable, re-identifiable (coded) or non-identifiable*
* *Where the data will be kept and who will have access to it*
* *How long it will be stored and what will happen to the data at the end of the storage period (Refer to your institution’s policy on retention of study data)*
* *Whether the participant is being asked to provide consent for the use of their data for this project only, or for extended (related research) or unspecified (any future research) use of their data*

**Examples of statement**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. [*Explain how it will be confidential and, if it is identifiable, where it will be kept and who will have access to it*]. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collect and use is [*types of information, e.g. information from questionnaires*].

* 1. **What about compensation and complaints?**

*You should inform participants how complaints will be handled and what redress may be available. Clarify whether there is a procedure in place for this and, if so, what the procedure is. You will need to distinguish between complaints from participants regarding their treatment by members of staff/the research team and something serious happening during or following their participation in the research project.*

**Examples of statement:**

You will not be paid to take part in the study; however, we will make sure that you don’t bear additional costs from your participation. All diagnostic tests will be free of charge, as well as the treatment you may need during your participation. If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

* 1. **Who is organising and funding the research?**

*Organising and funding research.* *Where commercial sponsorship is available, provide the international sponsor (if applicable)*

**Examples of statement:**

This research project is being conducted by [*Name of person*].

This research is being conducted by [*name of international sponsor*].

It is being funded by [*Name of funding organisation and address*].

* 1. **Who has reviewed the research project?**

*All research in Rwanda involving humans is reviewed by an independent Ethics Committee and approved on the competent Authority (Rwanda FDA) in case they involve regulated products*

**Examples of statement:**

The ethical aspects of this research project have been ethically cleared by [ *RNEC/IRB of* *institution*] and approved by Rwanda FDA. This project will be carried out according to the principles of Good Clinical Practices and other regulatory requirements which has been developed to protect the interests of people who agree to participate in human research studies.

* 1. **Further information and who to contact**

*List the names and contact phone numbers of other appropriate persons involved in the project including researchers and study coordinators.*

**Examples of statement:**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the principal investigator on [*insert Names, Positions, Phone number, e-mail Adress*] or any of the following Research contact persons and Research site manager [*insert Names, Positions, Phone number, e-mail Adress*]*:*