University of Fort Hare
Together in Excellence

UFH HREC Stamp

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

PRINCIPAL INVESTIGATOR:

ADDRESS:

CONTACT NUMBER:

You are being invited to take part in a research project that forms part of my..... Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher any questions about any part of this project that you do not fully understand. It is very important that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you did agree to take part.

This study has been approved by the **University of Fort Hare Health Research Ethics Committee (UFH HREC) (Ref No…….)** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki and the ethical guidelines of the National Health Research Ethics Council. It might be necessary for the research ethics committee members or relevant authorities to inspect the research records.

What is this research study all about?

- *This study will be conducted .....and will involve..... with experienced health researchers trained in ..... X participants will be included in this study.*
- *The objectives of this research are:*

Why have you been invited to participate?

- *You have been invited to participate because you are ……*
- *You have also complied with the following inclusion criteria:*

- *You will be excluded if:*

What will your responsibilities be?

- *You will be expected to ……*

Will you benefit from taking part in this research?

- *The direct benefits for you as a participant will be ……..*
- *The indirect benefit will be……..*

Are there risks involved in your taking part in this research?

- *The risks in this study are ……*
- *The benefits outweigh the risk*

What will happen in the unlikely event of some form of discomfort occurring as a direct result of your taking part in this research study?

- *Should you have the need for further discussions after the..... an opportunity will be arranged for you to.....*

Who will have access to the data?

- *Anonymity will ..... Confidentiality will be ensured by ..... Reporting of findings will be anonymous by..... Only the researchers and..... Data will be kept safe and secure by locking hard copies in locked cupboards in the researcher's office and electronic data it will be password protected. (As soon as data has been transcribed it will be deleted from the recorders.) Data will be stored for ….years.*

What will happen with the data/samples?

- *This is a once-off collection and data will……..*

Will I be paid to take part in this study and are there any costs involved?

No/Yes. You will/will not be paid to take part in the study but refreshments will be..... Travel expenses will be paid for those participants who have to travel to the site..... There will thus be no costs involved for you if you do take part.

Whom can you contact for additional information regarding the study?

The primary investigator……., can be contacted during office hours at Tel:....., or on his cellular phone at …….. The study leader, ……., can be contacted during office hours at Tel: ……. The co-study leader…….... can also be contacted during office hours at Tel ……. Should you have any questions regarding the ethical aspects of the study, you can contact the Chairperson of the UFH HREC, Prof DT Goon, during office hours at Tel 043 704 7368.

How will you know about the findings?

- The findings of the research will be shared with you by…….

Declaration by participant

By signing below, I ……...……. agree to take part in a research study titled:

I declare that:

- I have read this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions to both the person obtaining consent, as well as the researcher, and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..…….. on (*date*) ……...……. 20…

....

Signature of participant **Signature of witness**

Declaration by person obtaining consent

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter.

Signed at (*place*) .....….....…….. on (*date*) ……...…….. 20....

....

Signature of person obtaining consent **Signature of witness**

Declaration by researcher

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter.

Signed at (*place*) .....….....…….. on (*date*) ……...…….. 20....

....

Signature of researcher **Signature of witness**