**The Foundation for Professional Development Research Ethics Committee (FPDREC)**

***Pro Forma***

**PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT**

*(Each participant must receive, read, and understand this document before the start of the study)*

**STUDY NUMBER: …………...**

**STUDY TITLE**

Give a complete and full description of the study

**SPONSOR**

Give details of the sponsor if applicable

**INTRODUCTION**

You are invited to take part in a research study to be conducted by the Principal Investigator, Dr/Mr/Me ……………………… on behalf of the abovementioned sponsor. This document is to help you to decide if you would like to participate in this study. You should fully understand what is involved before you agree to take part in this study. If you have any questions that are not fully explained in this document, do not hesitate to ask the Principal Investigator. You should not agree to take part unless you are completely satisfied about all the processes and procedures involved and possible risks. You should be 18 years or older to participate in this study.

**STUDY INFORMATION**

**PURPOSE**

Give a full description of the purpose and objectives of the study

**DURATION**

Give detail of duration and any visits to and or meetings with the participant.

**WHAT WILL YOU BE REQUIRED TO DO IN THE STUDY?**

If you decide to take part in the study, you will be required to do the following:

Provide detail of what requirements are.

**ETHICAL APPROVAL OF STUDY**

The Protocol of this study was submitted for approval to the Foundation for Professional Development Research Ethics Committee (FPDREC), a research ethics committee registered with the National Health Research Ethics Council. Written approval has been granted by the FPDREC for the conduct of the study. The study has been structured in accordance with the Department of Health: Ethics in Health Research: Principles, Processes and Structures, Second Edition, 2015 and other national and international guidelines. Copies of these documents may be obtained from the Principal Investigator should you wish to review it.

**YOUR RIGHTS AS A PARTICIPANT IN THIS STUDY**

Your participation in this study is entirely voluntary and you can refuse to participate, or you can stop at any time without stating any reasons whatsoever. Your refusal to participate or your withdrawal will not affect your access to health care. The Principal Investigator, however, retains the right to withdraw you from the study if it is considered to be in your best interest.

**STUDY PROCEDURES MAY RESULT IN DISCOMFORT OR INCONVENIENCE**

Give detail if any discomfort or inconvenience is envisaged as well as the possible solution.

**THE RISKS INVOLVED IN THIS STUDY**

Give detail of any risks involved by participating in the study as well as possible solutions.

**WARNINGS OR RESTRICTIONS CONCERNING YOUR PARTICIPATION IN THIS STUDY**

Provide detail if applicable

**CONFIDENTIALITY**

Your participation in this study is entirely anonymous. Your identity will not be revealed while the study is being conducted or when the study is reported in scientific journals.

All identifying information about you will be kept in a locked file cabinet. This data will not be available to anyone who is not part of the study and will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly. All of these people are required to keep your identity confidential. Records that identify you will be available only to people working on the study unless you give permission for other people to see the records.

Please note that it is a group discussion, and you will share information with others, and they will share their information with you. We are unable to control what other participants will do with the information they hear and so cannot guarantee confidentiality from them. You may participate under a pseudonym [false name] if you prefer.

We are asking you to give us permission to tape-record the group session so that we can accurately record and transcribe what you think and say. The information you give may be collected via diagrams or graphic representations for statistical information. Your answers will be stored electronically on a single dedicated hard drive, when not in use in a locked file cabinet and these audio files will be used only for research purposes now or at a later date in ways that will not reveal who you are.

We will not record your full name anywhere and no one will be able to connect you to the answers you give. Your answers will be linked to a fictitious code number, and you are welcome to use a pseudonym (another name) and we will refer to you in this way in the data, any publication, report, or other research output.

Your data records will be kept for two years and thereafter will be destroyed. Paper records will be shredded and recycled. Records stored on a computer hard drive will be erased using software applications designed to remove all data from the storage devices. Data stored on USB drives and tape recorders, CDs, or DVDs, and other storage devices will be physically destroyed. A record showing which data was destroyed, and when and how it was destroyed will be kept in a safe cabinet.

The information received during the study will only be used for research purposes. The results of this study might be published in a scientific journal and/or presented at scientific meetings, but again without revealing the identity of any research participant.

(The above is merely an example. Please provide detail of situation re the specific study)

**BENEFITS**

There are no immediate benefits to you from participating in this study. However, this research will be extremely helpful to us in that we hope it will ultimately promote.............. (give detail). Your contribution might, in a small way, go towards benefiting the community.

**FINANCIAL ARRANGEMENTS AND COMPENSATION**

Out-of-pocket and/or travel expenses relating to the study will be reimbursed adequately. (The amount to be paid may be stated) Also provide details of any snacks provided to participants during interviews if applicable

**Or**

You will not be paid to participate in the study.

**SOURCE OF ADDITIONAL INFORMATION**

If you have concerns or questions about the research you may call the Principal Investigator, (Provide name and contact detail)

If you have any queries, concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the FPDREC on Tel no: 087 821 1109 or by email on [Liviav@foundation.co.za](mailto:Liviav@foundation.co.za).

**INFORMED CONSENT**

I hereby confirm that I am 18 year and older and have been informed by the study Principal Investigator, Dr/Mr/Me (detail of person obtaining consent) ............................................................................., about the nature, conduct, benefits, and risks of this study (title)............................. I have also received a copy of this document and I have read and understood the content of the document.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

I consent that the proceedings be recorded during the interview and understand that the recordings will be kept confidential until such time as they are destroyed.

I may, at any stage, without prejudice, withdraw my consent and end my participation in the study.

I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Participant:

Printed Name Signature Date

I, Dr/Me/Mr (Principal Investigator or person obtaining consent) ........................

........................................................................................................................

herewith confirm that the above participant has been informed fully about the nature, conduct and risks of the above study.

Principal Investigator or person obtaining consent:

Printed Name Signature Date

Witness Identification

Witness:

Printed Name Signature Date

***(*Witness’s signature confirms that he/she has witnessed the relevant signatures at the time of signing. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the participant and the person obtaining consent. A competent witness is a person 16 years or older and of sound mind and not involved with the trial.)**

**VERBAL INFORMED CONSENT**

(This section is applicable when participants cannot read or write and should replace the previous Informed Consent section)

I, the undersigned Principal Investigator / person obtaining consent, Dr/Mr/Me

......................................................................................................................................, has read and have explained fully, to the participant, named.............................. and/or his/her relative, as well as the witness who signed below, with the consent of the patient, the content of this document, indicating the nature and purpose of the study in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study. The participant indicated that he/she is 18 years or older, understands the content of the document and that he/she will be free to withdraw from the study at any time for any reason without jeopardy. I have also informed the participant on the existence of relevant compensation arrangements.

I hereby certify that the participant has agreed to participate in this study.

Patient:

Printed Name Signature or mark Date

Principal Investigator or person obtaining consent:

Printed Name Signature Date

Witness Identification

I, the witness who signed below, confirm that the Principal Investigator or person obtaining consent has explained fully the content of this document to the participant.

Witness:

Printed Name Signature Date

***(*Witness’s signature confirms that he/she has witnessed the relevant signatures at the time of signing. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the participant and the person obtaining consent. A competent witness is a person 16 years or older and of sound mind and not involved with the trial.)**