**STUDY INFORMATION DOCUMENT**

**Study title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Greeting** (Do not address the reader presumptively as a “Participant,” as they have not agreed to participate as yet):

**Introduction:**

[Example] I / We, …………………., are doing research on …………. . Research is a process used in seeking new knowledge. In this study we want to learn …… (Include information that this is a study involving research and not routine care and why the study is being done).

**Invitation to Participate:**  We are asking / inviting you to take part in a research study (or asking for your permission to include your child in a research study).

**What is involved in the study. This could include but would not necessarily be limited to such features as:**

1. Study design, what the Participant’s involvement in the study would entail;
2. If the study starts and end dates can confidently be foreseen, please mention them;
3. Standard procedures being done in the study and procedures that are being tested in the study;
4. Where the procedures will be done and how long the procedures will take to carry out (how much of the Participant’s time is required);
5. If a questionnaire is to be used, how is it to be distributed and collected, if in hard copy; if it is to be conducted online, please say so and remind the reader that engaging in the online process implies that he or she has consented to take part in the study;
6. What sort of questions would be asked and how long the questionnaire would take to be completed; and /or
7. If blood samples are to be taken, then how much blood (teaspoons) and how frequently?

**Risks of being involved in the study:** A description of the procedures for handling adverse events and what arrangements have been made for compensation. If it may reasonably be anticipated that the Participant might find the proceedings traumatic, what arrangements have been made to provide him or her with free professional counselling or alternate treatment?

**Benefits of being in the study:** In many studies, there is no direct benefit to the Participant and they should be told this. In some studies, the longer-term objective is the possibility of better treatment for subsequent patients and if so, it may assist prospective Participants to see the importance of their role if they are told this.

The Participant will be given pertinent information on the study while involved in the project; after the results are available, the participant should be offered a free results summary, on request.

**Participation is voluntary:** refusal to participate will involve no penalty or loss of benefits to which the Participant is otherwise entitled, as,for example*,* a hospital patient; the Participant may discontinue participation at any time without penalty, or loss of benefits to which the Participant is otherwise entitled; that there is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless the Participant specifically consents to its retention.

**Reimbursements for “out of pocket” expenses** may be allowed, but there is to be no payment or cost associated with participation, *e.g.,* travel expenses and refreshments; if this is a set amount, please say how much it is.

**Confidentiality**: Normally personal information will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and his/her Supervisor, in the case wherein the PI is a postgraduate student. The only exceptions - and all of them are rare - would normally be:

1. personal information may be disclosed if required by law
2. the Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint, or for a compliance audit
3. the South African Health Products Regulatory Authority (SAHPRA) might conceivably require access to personal data, if conducting an investigation into a drug trial

Where a study involves focus group discussions, Participants may very well recognize each other and while the PI may request confidentiality, he/she is not in a position to enforce it. For the same reason, anonymity cannot be guaranteed in focus group discussions.

Participants should be assured that no individual will be identified by name in any report or publication arising out of the study. All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly.

**Anonymity** can usually only be guaranteed in questionnaires, whether in hard copy or online

**Contact details of researcher/s:** to enable prospective or actual Participants to get further information, or report adverse events, please provide e-mail and telephone contact details of the Principal Investigator and his/her Supervisor.

**Outputs**

Tell the reader what the outputs of the study will be and offer to share them with him/her after the study is completed

**Contact details of HREC administrator and chair** – for reporting of complaints / problems. The following text is recommended:

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg (“Committee”). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Paul Ruff, who may be contacted via any one member of the secretariat. The telephone numbers for the Committee secretariat are 011 717 2700/1234/2656/1252 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za, Rhulani.Mukansi@wits.ac.za, Mapula.Ramaila@wits.ac.za and Iain.Burns@wits.ac.za.

Thank you for reading this Study Information Sheet.

Date: Month and Year only

**Non-standard items which may be included where appropriate**

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant’s consent.
3. Where genetic tests are to be done, a separated information sheet and consent form will be made available.
4. A statement that specimens would be stored for future research pertaining to the specific research question being studied and a separate participation information sheet and consent form will be made available. Specify how long specimens will be stored for, where they will be stored and whether these will be anonymised. If stored for future genetic testing, a further consent form will be signed.
5. If children (defined as persons below 18 years of age) are included as participants, it is likely that it will be necessary to produce a simplified version of the Information Sheet, using language or images and concepts which they are likely to understand and offering to help explain any points which are unclear to them. They will need reassurance that their parents or guardians know about the study and are willing to have the children participate, if the children so wish, *i.e.* both parties must agree to the child’s participation.
6. A distress protocol may be necessary in the case of anticipated research-induced distress. *e.g.* questions that address issues of abuse, abandonment, previous negative sexual experiences, or traumatic memories may induce distress in the participants. A distress protocol must include the name and contact details of the registered counsellor who will provide the counselling, at no cost to the participant.

January 2023