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| **FACULTY OF MEDICINE & HEALTH SCIENCES** **WALTER SISULU UNIVERSITY HEALTH RESEARCH ETHICS COMMITTEE** |

**Consent Document Guide**

*(Kindly type in all details)*

**Research Project Title**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Ethical Clearance Number**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*will be available after submission to the HREC*).

PRINCIPAL INVESTIGATOR

[Name]

[Department]

[Address]

[Phone]

[Email]

PURPOSE OF STUDY

The purpose of this study is to [Briefly describe purpose of study.]

**The consent document needs to address the following questions/ concerns (where appropriate or depending on the research topic)**:

1. Participation in this project is voluntary.
2. Participants to understand that they will not be paid for their participation.
3. Participants be assured that they are allowed to withdraw and discontinue participation at any time without penalty or prejudice to services.
4. If participants decline to participate or withdraw from the study, they will not be prejudiced.
5. Participants must be made to understand that they have the right to decline to answer any question or to end the interview at any given point if they find it necessary.
6. Participants understand processes involved in data collection of the study.
7. List and explain the any possible or anticipated risks of participating in this research or of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.
8. List and explain the benefits of each of participating in this research (benefits can be individual, benefits to the community in which the individual resides, and benefits to society as a whole).
9. Participants understand the number of legs/ phases or approximate number of participants targeted in this study.
10. Participants understand that the researcher will keep their identity anonymous in any reports using information obtained from the study. Participants’ confidentiality in the study will remain secured. Explain what will/ must happen when there is breach of confidentiality?
11. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions.
12. Precaution to be applied to prevent my individual comments from having any negative repercussions.
13. Participants to be informed so that they understand that the research study has been reviewed and approved by the accredited HREC for Studies Involving Human Participants and have seen the Ethics Approval. Include details of the approving HREC.
14. Must be given time to read and understood the explanation provided to them as participants.
15. Participants must confirm that all their questions are answered to their satisfaction, and voluntarily agree to participate in the study.
16. Participants must be provided with a copy of this consent form/study information sheet reflecting the above protection provisions.
17. Empowerment of the participant- who will take the IC? What will be the process? Move at the pace of the participant? Bring own witness? Privacy? Who else will join the process? Dealing with misconceptions e.g., therapeutic, continuous checking of participant’s understanding, setting, relationship with the prospective participant, who will take the IC- their training, role, qualifications, etc.
18. Declare conflict of interest.
19. Time to consider before signing the consent document, how will be the study be publicized?
20. How long will the session take?
21. Question and answer session at the end / comprehension of the questionnaire/ data collection tool especially for Randomised Clinical Trials.

**CONTACT INFORMATION**

If at any time you have any questions about this study or experience side effects as a result of participating in this study, you may contact the researcher whose contact information is provided above. If you have questions about your rights as a research participant or if you encounter any issues that you feel cannot be discussed with the principal investigator, please contact:

[Add REC contact details]

Also include the following:

**CONSENT**

I have read and understood the information provided (or the data collector clearly explained it to me) and had the opportunity to ask questions. I am aware that my participation is voluntary and that I can withdraw from participation at any time without giving reasons and at no cost. I understand that I will be given a copy of this declaration of consent. I voluntarily agree to take part in this study.

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Participants Signature Date

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PI Printed Name Signature Date

For further information, please contact:

Dr. [Name of Principal Researcher] [Contact Information of PI]

In case of complaint/s in relation to the application to the study contact The Chairperson, Walter Sisulu Health Research Ethics Committee. Tel: 047 502 2092/ 2093 or email address: fhsrec@wsu.ac.za.