**NELSON MANDELA UNIVERSITY**

**Research Ethics Committee: Human (REC-H)**

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# INFORMED CONSENT TEMPLATE

*Note to researchers (to be deleted by researcher):*

 *Please ensure the scientific and legal accuracy of all information that is presented here. Make sure that the form is written in simple and clear language that is easily understandable by participants. The language should be adapted to suit the specific needs and comprehension levels of your target group. Where necessary, please provide translated versions of the form.*

*\*This is a template and should be adapted to your specific research requirements.*

**Information Sheet**

 **(Edit accordingly, the information in the brackets is there to guide you)**

Date:

Greeting: (insert appropriate greeting)

My name is (your name), and I am a (your position i.e., staff/student) at the (name, department/institution). I can be contacted on (include your NMU email address and phone number) and my supervisor can be contacted on (include your supervisors email address and phone number).

**Study Procedures**

You are being invited to consider participating in a research study titled (insert study title) under the supervision of (provide details). The study aims to (describe in lay terms what the aim and purpose of your research is). It will involve the following procedures (describe the procedures and methods). The duration of your participation if you choose to enroll and remain in the study is expected to be (indicate estimated time required from participants). Data collection will take place at (add location details; if it is online indicate the platform). The following personal information will be collected for the purposes of the study (if any, explain which bits of personal information will be collected and how you will comply with POPIA. And if from secondary data – how).

**Risks and benefits**

The study may involve the following risks and/or discomforts (describe any potential risks, discomforts and/or benefits). (Describe the anticipated study contribution scientifically and if there will be no direct benefits, please indicate that here so that the participant is aware). Additionally, (if the study has any risks for which the participant will be compensated (e.g. counselling services, medical treatment, please indicate so and where this can be obtained and who will cover the costs).

**Compensation**

(Indicate any costs that they will incur as a result of participation, incentives and reimbursements. Indicate how much, why and when this will be paid. Also indicate where a cost will not be or cannot be refunded / reimbursed). If there is no compensation, delete this section.

**Data Storage and Disposal**

Your data will be stored (provide details). It will be kept confidential and anonymous (explain any exceptions, who will have access and how will access be restricted from everyone else). Indicate for how long data will be stored and how and when it will be discarded).

**Voluntary Participation and Withdrawal Procedures**

Please note that your participation is voluntary, and you can withdraw at any time without penalty or consequence (If there are any limitations to the withdrawal process please explain. For instance, if data provided truly anonymously will not be able to be deleted should the participant decide to withdraw from the study or whether it will be destroyed). To withdraw from the study, (indicate the withdrawal procedure so that they are aware).

Please note that the ethical integrity of this study has been reviewed and approved by the Research Ethics Committee (Human) of Nelson Mandela University (NMU). This committee consists of a group of independent experts that have the responsibility to ensure that the rights and welfare of participants in research are protected and that studies are conducted in an ethical manner. The approval number is \_\_\_\_\_. The approval letter is also attached.

**Contact Information**

Should you have any queries or concerns pertaining to the study or your rights as a participant, you may contact the researcher on the contact details provided above, or the NMU Research Ethics Committee on 27 41 504 2538 or rd@mandela.ac.za. Concerns or queries that have not been satisfactorily addressed by the NMU RECH can be directed to the National Research Ethics Committee (NHREC) via email at nhrec.gov.za. Where relevant, concerns or complaints regarding the use of medical products or equipment should be directed to the South African Health Products Authority (SAHPRA) at <https://www.sahpra.org.za/whistleblower/>.

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**Consent Form**

**(Edit as per your study requirements and needs and a copy must be given to the participant)**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(participants name) have been informed about the study entitled (add your study title) by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(provide name of researcher/fieldworker).

I declare that:

I understand my participation is voluntary and I can withdraw at any time without penalty or consequence.

I have been given an opportunity to ask questions about the study and I am satisfied with the answers I received.

The potential benefits, risks and discomforts have all been clearly explained to me.

I have been informed about any available compensation or medical treatment available to me should I require it as a result of study-related procedures.

I have been informed and consent to my data being stored and discarded according to the described measures.

**Additional consent, where applicable (delete what is not relevant to your study)**

I hereby provide consent to:

Audio-record my interview / focus group discussion YES / NO

Video-record my interview / focus group discussion YES / NO

Use of my photographs for research purposes YES / NO

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name of Witness (Where applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name of Translator (Where applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Translator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***If illiterate***

 ***A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well)***

**I have read the consent form aloud to the potential participant, and they have had the opportunity to ask questions. I confirm that the participant has freely given their consent.**

**Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_Thumb print of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**