**PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR ADULT PARTICIPANTS**

Form #: **ICF 02**

**HOW TO USE THIS CONSENT FORM:**

This document is the REC-approved template to assist you with designing a written informed consent form. You may adapt the template as you see fit, but remember that the document must address the participant directly, include information about each heading, and feature the SU logo at the top. **Please write in PLAIN, NON-TECHNICAL language**.

The text written in *[RED]* serves only as a guide and should be replaced with the relevant project information before finalising the document. Additionally, this information box must be removed prior to finalising the document.

**TITLE OF THE RESEARCH STUDY:** [*insert]*

**PROJECT ID:** [*insert study ID as it appears on the REC Application form]*

**PRINCIPAL INVESTIGATOR/RESEARCHER:** [*insert]*

1. **INTRODUCTION**

We would like to invite you to take part in a research study. Please take some time to read the information below which will explain the details of this research study

1. **WHO IS CONDUCTING THIS STUDY?**

This research study is conducted by [*insert your name and the names of other researchers involved in the study*].

The researcher(s) (is/are) from the [*insert your SU department*] at Stellenbosch University.

*[Kindly provide details: state who ‘we’ relates to, that is, whether you are a student registered at Stellenbosch University for a specific degree or part of a research team (names of the team members) and so forth.]*

1. **VOLUNTARY PARTICIPATION**

Your participation is completely voluntary, and you are free to decline to participate. In other words, you may choose to take part, or not. Saying no will not affect you negatively in any way whatsoever.

You are also free to withdraw from the study at any point, even if you do agree to take part initially. [*Please amend this statement if participants are required to withdraw before a specific point in the study; is there a reasonable point in the study where you will not be able to withdraw a participant’s data/information?]*

Please feel free to contact the researchers about any part of this study that you do not fully understand. It is very important that you are completely satisfied that you clearly understand what this research is about and how you could be involved.

1. **WHY DO WE INVITE YOU TO PARTICIPATE?**

[*Explain clearly why you are inviting this person to take part in this study? What qualifies them to be a participant?]*

1. **WHAT IS THIS RESEARCH STUDY ABOUT?**

[*Explain in participant-friendly language what your study aims to do and why you are doing it. Imagine having a conversation with one of your participants. Write in plain English and use the active form; avoid passives as far as possible. This applies to all text that you add to this form.*

*Remember this consent form will be read by your participant – please do not copy-and-paste from your research proposal*]

1. **WHAT WILL BE ASKED OF ME?**

If you agree to take part in this study, you will be asked to

[*describe in simple, non-technical language* ***all the activities*** *the participant will be invited to take part in for this study; what they will be asked to do. All activities and scientific terms should be well-defined and explained in participant-friendly language. Make sure you indicate the length of time estimated for participation in each activity, the frequency of these activities, the location where activities will be done, etc.* *Also mention if there is anything that your participant will be responsible for when they agree to take part in the study*. *Explain the procedures – focus groups, in-depth interviews, questionnaire interviews, etc.]*

**[Sample text for Interviews]**

*If you agree to participate in this study, you will be asked to complete an online questionnaire. The questionnaire will take approximately [insert estimated time, e.g., 10–15 minutes] to complete. It will include questions about your [insert general topics, e.g., experiences, opinions, or behaviours related to the study topic].*

*The following types of personal information will be collected:*

* *Age*
* *Gender*
* *Educational background*
* *Employment status*

*[Add any other general personal data relevant to your study]*

*Depending on the focus of the study, the questionnaire may also include questions that fall under 'Special Personal Information' as defined by the Protection of Personal Information Act (POPIA), such as:*

* *Religious or philosophical beliefs*
* *Race or ethnic origin*
* *Trade union membership*
* *Political opinions or persuasion*
* *Health-related information*
* *Sex life or sexual orientation*
* *Biometric data (e.g., fingerprints, facial recognition)*
* *Information regarding alleged or actual criminal behaviour*

*Please note that all responses will be collected anonymously and used solely for research purposes. You are free to skip any questions you are uncomfortable answering.*

*During the interview I will write down what you say. With your permission, the interview will be recorded on a recording device to ensure that no information is missed. We will use a voice recorder to make sure we record your words exactly how you said them. The notes and the recording will not contain your name or other identifying information and will be stored on a computer that is password protected. The audio recordings will be destroyed after 5 years.*

[**Sample text for Focus Group Discussions]:**

*During the focus group discussion, you may find that some questions are sensitive; for instance, questions about [insert sample questions]. You do not have to share any information you are not comfortable with.*

*If questions feel too personal or make you uncomfortable, you do not have to answer them.*

*If you need psychological support or counselling during or after the focus group discussion, you can contact [insert contact details of counsellor/psychologist – if applicable]*

**Sample text for self-administered questionnaire]**

*This study involves answering some questions regarding your [insert subject matter]. We would like you to complete a questionnaire. It will take approximately \_\_\_\_ minutes. The researcher will keep the completed questionnaires in a safe place to make sure that only people working on the study will have access to it. Please do not write your name on the questionnaire. This will ensure that your answers are kept confidential (so nobody will know what you have answered).*

1. **ARE THERE ANY RISKS IN MY TAKING PART IN THIS RESEARCH?**

*[Explain (objectively) the anticipated risks, discomforts, inconveniences, and discuss how you will address or manage these risks to protect the participant (e.g., referral for counselling or therapy, reimbursement of any costs e.g., transport, etc.). Make sure the risks listed here align with the risks you identified in your REC application and proposal].*

1. **CONFIDENTIALITY**

**(Please refer to the sample texts below for guidance on what to include and delete what is not relevant to your study).**

**[Sample text for Focus Group Discussions/Interviews]**

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

*All records from this study will be regarded as confidential. Results will be published in research journals or presented at conferences in such a way that it will not be possible for people to know that you were part of the study.*

*The records from your participation may be reviewed by people responsible for making sure that research is done properly. All these people are required to keep your identity confidential. Otherwise, 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.*

*All hard copy information will be kept in a locked facility at ………………………….. at the Stellenbosch University, for a minimum of …….…. years and only the research team will have access to this information. (Also state where electronic version of the information will be stored and in what format, length of storage and access. It is recommended that you use SU One Drive or platforms recommended by Stellenbosch University's IT department)*

***[For Focus Group Discussions only]****: Although all participants of the focus group discussion will be requested to keep the discussion confidential, the researcher cannot guarantee that they will do so. I therefore request that you do not disclose any information of a very personal or sensitive nature during the group discussion.*

***[Sample text for Survey Questionnaire]***

*We will not record your name anywhere and no one will be able to connect you to the answers you give. Your responses will be assigned a unique identification code, and we will refer to your data only by this code in any publication, report, or other research output.*

*All data collected from this survey will be treated as confidential. Results will be published in research journals or presented at conferences in such a way that individual participants cannot be identified.*

*The data from your participation may be reviewed by people responsible for ensuring that research is conducted properly. All these individuals are required to maintain your confidentiality. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for others to see the records.*

*All survey data will be kept in a password-protected electronic format on secure servers at ……………………… at Stellenbosch University, for a minimum of ……… years, and only the research team will have access to this information. (Also state where electronic version of the information will be stored and in what format, length of storage and access. It is recommended that you use SU One Drive or platforms recommended by Stellenbosch University's IT department).*

1. **WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH?**

*[Explain (objectively) the direct, personal benefits that participants can expect when taking part in this study. If there are no personal benefits then indicate who would be likely to benefit from this research, e.g., society, future participants, etc.]*

1. **WILL I BE PAID TO TAKE PART IN THIS STUDY AND ARE THERE ANY COSTS INVOLVED?**

*[State whether the participant will receive payment or whether the participant will be compensated for any expenses paid to take part in the study (e.g., compensated for transport costs, entry into lucky draws). If not, state so clearly. If participants will receive payment, state the amount, state when payment can be expected, and describe the proration schedule should the participant decide to withdraw.]*

*[Participants should not have to pay for anything if they agree to take part in the study. If there are certain costs involved for the participant, please state how they will be compensated or reimbursed for each cost. The amount and method of payment to research participants should reflect the following three components:*

* *Compensation for time.*
* *Compensation for inconvenience; and*
* *Reimbursement of expenses.]*

1. **WHO WILL HAVE ACCESS TO MY INFORMATION?**

Any information you share with me during this study and that could possibly identify you as a participant will be protected.

[*Describe the measures/steps you will take to ensure anonymity and respect the privacy of the participant. You should share information about the following:*

* *where and how their data will be stored and secured?*
* *who will have access to their data, and for what purpose?*
* *will you identify participants or organisations in the research report, publications or presentations? If YES, then explicit, written consent must be obtained from the participant and/or the organisation (if applicable) to identify them in the report.*
* *Will the raw data be released to or shared with any other person/third party for any reason? If yes, please identify the person/third party with whom the raw data will be shared, specify the information that will be shared with them and the reason the data will be shared. The participant must provide explicit, written consent for their data to be shared with other researchers or third parties (even if it will be de-identified before sharing).*
* *Will their raw data or personal information be shared outside the borders of South Africa i.e. internationally?*
* *State whether the information collected for this study will be used for future publications and/or used for other purpose in the future].*

[*If activities will be audio-recorded, photographed or videotaped, mention this here and state whether the participants will have the opportunity to review/edit the tapes, who will have access to these recordings, if they will be used for educational purposes, and when they will be erased.*]

*[If you plan on publishing the results of the study describe how confidentiality and/or anonymity will be maintained in the publication]*

1. **HOW DO I CONTACT THE RESEARCHERS?**

If you have any questions or concerns about this study, please feel free to contact the researcher, *[Researcher’s name and surname]* at *[enter your SU contact information],* and/or the study supervisor *[Supervisor’s name and surname]* at *[Supervisor’s SU contact information].*

[*Please use your SU email address and contact information for contact purposes. We advise our researchers not to use their personal contact details for their own protection and to ensure adequate boundaries between personal and professional activities*]

1. **RIGHTS OF RESEARCH PARTICIPANTS**

*[The information below must be included in your consent form. This is a regulatory requirement which states that an institutional contact person must be provided to participants if they want to raise concerns or questions*]

In accordance with the Protection of Personal Information Act (POPIA), you have the right to be informed about the collection and use of your personal information. This includes the right to access the information you have provided and to request corrections if any of it is inaccurate or incomplete.

If you have any questions, concerns, or complaints regarding your rights as a research participant, or if you wish to exercise your rights under the Protection of Personal Information Act (POPIA), please contact the Research Ethics Committee at [applyethics@sun.ac.za; 021 808 9183].

1. **RESEARCH ETHICS APPROVAL**

This study has been approved by the **Research Ethics Committee: Social, Behavioural and Education Research at Stellenbosch University (Study ID#…).** The study will be conducted according to the ethical guidelines and principles of South Africa’s Department of Health- South African Ethics in Health Research Guidelines: Principles, Processes and Studies (NDoH 2024) and *[insert any other guidelines/code of conduct which applies to your field of research].*

1. **OFFER TO ANSWER QUESTIONS**

**Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.**

**SECTIONS TO INCLUDE IN YOUR CONSENT FORM WHERE APPLICABLE**

*Please delete this section if it does not apply to your study.*

**PERMISSION TO HAVE ALL ANONYMOUS DATA SHARED WITH JOURNALS:**

*Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study.*

When this study is finished, we would like to publish results of the study in journals. Most journals require us to share your anonymous data with them before they publish the results. Therefore, we would like to obtain your permission to have your anonymous data shared with journals. In accordance with the POPI Act, the researchers will take care to ensure that your is not identifiable (personal information is not linked to the data shared).

**PERMISSION FOR SHARING SAMPLES AND/OR INFORMATION WITH OTHER INVESTIGATORS:**

*Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect in anyway.*

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect you in any way.

To conduct the research as discussed, we must collect and store information (data) from you. Other qualified investigators, including those from outside South Africa, may request access to this data for future research.

In accordance with the Protection of Personal Information Act (POPIA) and the ASSAf POPIA Compliance Framework for Research, your data may be shared under strict conditions:

- The data will be securely stored at [INSERT STORAGE LOCATION] and managed by [INSERT RESPONSIBLE DEPARTMENT/INSTITUTION].

- Access will be limited to [INSERT WHO WILL HAVE ACCESS, e.g., the primary research team and authorized collaborators who have signed confidentiality agreements].

- If data is shared across borders, we will comply with Section 72 of POPIA, ensuring that:

* + The receiving country has adequate data protection laws, or
  + Binding agreements are in place to ensure equivalent protection.

To protect your privacy:

- Your name will be replaced with a unique study number.

- All data will be de-identified before sharing.

- We will implement appropriate technical and organisational safeguards as required by the Research Ethics Committee (REC) and the Division for Information Governance.

Although we take every precaution, there remains a minimal risk that someone could identify you from the data. However, this is highly unlikely due to the strict security and de-identification measures in place.

Before sharing any data, we will ensure:

1. All data is properly de-identified

2. Appropriate data transfer agreements are in place

3. Recipients have adequate data security measures

4. The use of the data aligns with the original purpose of collection

5. All relevant regulatory and ethical approvals are obtained

We ask for your permission to share your de-identified data under these controlled conditions:

**PERMISSION TO STORE INFORMATION/ DATA** *(including audiotapes, photographs and videotapes)* **for future studies:**

*Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study.*

As science and technology evolve, new research methods may become available that allow researchers to gain further insights from existing data. Instead of returning to participants for additional data, researchers may use previously collected data for future studies.

We request your permission to store the following data collected from you: [e.g., audiotapes, photographs, videotapes, etc.].

All future use of this data will:

* Require approval from the Research Ethics Committee: Social, Behavioural and Education Research (REC:SBE) at Stellenbosch University
* Comply with the ASSAf POPIA Compliance Framework and POPIA
* Be subject to oversight by the Division for Information Governance

If data is shared internationally in the future, we will ensure that:

* The receiving country has adequate data protection laws, or
* Binding agreements are in place to ensure equivalent protection

Your data will be de-identified and stored securely at [INSERT STORAGE LOCATION], managed by [INSERT RESPONSIBLE DEPARTMENT/INSTITUTION]. Only authorized personnel will have access.

We ask for your permission to store your de-identified data for future ethically approved research:

***For each statement, please choose YES or NO by inserting your initials in the relevant box)***

|  |  |  |
| --- | --- | --- |
| **Statement** | **YES** | **NO** |
| 1. I agree to having my photograph **taken** |  |  |
| 1. I agree to being **audio recorded** for study purposes |  |  |
| 1. I agree to being **video recorded** for study purposes |  |  |
| 1. I agree that my photograph/audio recording/video recording may be **stored for future studies** in ….*… [describe the field of your study].* |  |  |
| 1. I agree that my photograph/audio recording/video recording be shared with other researchers **in South Africa or outside** **South Africa** *(in other countries) (please adapt accordingly)* |  |  |
| 1. I agree to have my anonymous data shared with journals during publication of results of this study. |  |  |
| 1. My sample and/or information may be shared with other investigators **in South Africa or outside** **South Africa** *(in other countries) (please adapt accordingly)* who are able to conduct further analysis in *… [describe the field of your study].* |  |  |
| 1. I agree that my information (data) may be stored for future research in a field related to … *[describe the field of your study]* |  |  |

**DECLARATION OF CONSENT BY THE PARTICIPANT**

YOU ARE MAKING A DECISION ON WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO PARTICIPATE.

As the participant, I declare that:

* I have read this information and consent form, or it was read to me and it is written in a language in which I am fluent and with which I am comfortable.
* I have had a chance to ask questions, and I am satisfied that all my questions have been 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 nothing bad will come of it. I will not be penalised or prejudiced in any way.
* I agree that the interview with me can be [video-recorded / audio-recorded].

By signing below, I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name of participant)* agree to take part in this research study, as conducted by \_\_\_\_\_ *(name of principal investigator).*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Participant** **Date**

***YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP FOR YOUR RECORDS***

|  |
| --- |
| **DECLARATION BY THE PRINCIPAL INVESTIGATOR** |

I *(name)* ……………………………………………..……… declare that:

* I explained the information in this document to …………………………………..*(insert name of participant)*
* 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 (i*f a interpreter is used, then the interpreter must sign the declaration below).*

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

**Signature of investigator**

|  |
| --- |
| **DECLARATION BY THE INTERPRETER** |

***(Only complete if applicable – please delete if not applicable to your study)***

I *(name)* ……………………………………………..……… declare that:

* I assisted the investigator (*name*) ………….…………………………. to explain the information in this document to (*name of parent/legal guardian*) ……...………………………... using the language medium of Afrikaans/Xhosa etc.
* We encouraged him/her to ask questions and took adequate time to answer them.
* I conveyed a factually correct version of what was related to me.
* I am satisfied that the parent/legal guardian fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered.

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

**Signature of interpreter** **Signature of witness**