SOP 13: Informed Consent

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
Title	SOP 13: Informed Consent
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1. COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled for SACAP by	Dr Malesa Kgashane	6 August 2021	
Amended for SACAP by	REC Office	26 October 2021	K. J. Young
Checked by	Academic Manager	12 November 2021	C.E. Ford
Authorised by	Academic Dean	20 January 2022	J.O. Lotter

2. DOCUMENT HISTORY

Date	Version no	Reason for revision
July 2021	1	Development of the document

3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
SACAP REC	The South African College of Applied Psychology Research Ethics Committee

SOP	Standard Operating Procedure/s

4. PURPOSE OF THE SOP

The SOP on Informed Consent prescribes the process researchers/students and staff members of SACAP are required to follow to obtain informed consent from the respondents or participants taking part in the research.

5. ETHICS IN HEALTH RESEARCH: PRINCIPLES, PROCESSES AND STRUCTURES (DEPARTMENT OF HEALTH, 2015)

The following stipulations as per the *Ethics in Health Research: Principles, Processes and Structures* (Department of Health, 2015) apply to the SOP as indicated in the following clauses: 2.3.6., 3.2.5 & 3.3 regarding informed consent.

5.1. Personal information should be collected in adherence to the Protection of Personal Information Act 4 of 2013.

5.2. The participation of individuals should be based on their freely given, specific and informed consent. Researchers should respect participants' right at any stage to refuse to participate in particular aspects of the research or to decide to withdraw their previous given consent without demanding reasons or imposing penalties.

5.3. Participants should give their consent in writing and preferably accompanied by their signature. They, in turn, should be given written information containing adequate details of the research, including any risks associated with the study.

5.4. If participants refuse to provide their consent in writing, consent may be recorded verbally, if verbal consent can be linked to the individual providing such verbal consent. For example, where a participant is illiterate, consent should be obtained in the presence of a literate witness who should verify and sign a document stating that informed consent had been given.

5.5. Where the research is done on-line or electronically, informed consent can be obtained electronically but in a format separate from the on-line research in order to protect the identity of the participant.

5.6. Consent for participation in research is freely given and informed if:

5.6.1. It is given without any direct/indirect coercion or inducement;

5.6.2. Prospective participants have been informed on the processing and purpose of the intended research;

5.6.3. Prospective participants have understood this information and have indicated so;

5.6.4. The researcher has answered any question(s) about the research and their participation; and

5.6.5. It is given before research commences.

6. PROCEDURES

6.1. Access and complete the latest participant information sheet (*Annexure A4 of SOP 4: SOP 4 - Proposal Applications and Decisions Appeals and Monitoring*).

6.2. Insert the information as indicated on the template of this sheet.

6.3. Provide detailed information relevant to each question stipulated on this sheet.

6.4. Ensure that the section on consent to participate in this study is attached to the participant information sheet for the participant to complete and sign.

6.5. Ensure that the participant has received a copy of the participant information sheet and consent to participate well in advance of the study commencing or allow enough time for the participant to study the document.

6.6. If the participant cannot read, the researcher should ensure that an impartial witness is present when explaining the content of the documentation to the respondent or participant. The witness is required to attest to the fact that the researcher has accurately explained the information and that the respondent or participant has apparently understood the information presented to them and that consent thereafter was freely given. The witness will be required to sign a declaration in the informed consent form provided to participants by the researcher to this effect. To avoid any actual, potential, or perceived conflict-of-interest the witness may not be a family member or friend or colleague, but someone who's not involved in the design, data gathering or reporting of the study. (*Annexure A of SOP 13: Informed Consent*).

6.7. If the participant cannot speak English, a translator/interpreter fluent in English and the language understood by the participant can be used to explain the informed consent process. The interpreter/translator will be required to sign a declaration in the informed consent form provided to participants by the researcher to this effect. To avoid any actual, potential, or perceived conflict-of-interest the interpreter/translator may not be a family member or friend or colleague, but someone who's not involved in the design, data gathering or reporting of the study. (*Annexure A of SOP: Informed Consent*).

6.8. The witness and/or translator/interpreter will be required to sign a confidentiality agreement (*Annexure A: SOP 13: Informed Consent*) as well as tasked with the following in order to obtain voluntary informed consent prior to participants' formal participation in a study:

6.8.1. Reading the participant information sheet and consent to participate to the respondent or participant during a face to face data gathering exercise such as focus groups or interviews and other contact research data gathering sessions. It is advised that the nature and potential consequences of a study is explained to the participant in such a way that the participant can make an informed decision as to whether they wish to participate in the study.

6.8.2. Inviting questions from the participant regarding the information communicated to them.

6.8.3. Giving enough time for the participant to discuss or consider the information given to them.

6.8.4. Verify the information provided to the participant by checking whether the participant:

6.8.4.1. Understands the information given by the researcher;

6.8.4.2. Does not feel pressured to make a decision to participate or not;

6.8.4.3. Understands that there is a voluntary choice to participate;

6.8.4.4. Understands that they may withdraw at any time; and

6.8.4.5. Is able to make and communicate and make informed choices.

6.8.5. Assess whether the participant requires more information in which instance more explanation should be provided or that the participant is in fact incapable of giving consent.

7. REFERENCES

- Department of Health. (2015). *Ethics in health research: Principles, processes and structures.*
- Lui, M.B., & Davis, K. (2013). *A clinical trials manual from the Duke Clinical Research Institute: Lessons from a horse named Jim* (2nd ed.). Wiley-Blackwell.
- The Code of Federal Regulations (Title 21, Food and Drugs; Title 45; Part 46, Protection of Human Subjects).

ANNEXURE A:

CONFIDENTIALITY/NON-DISCLOSURE AGREEMENT: INTERPRETER/TRANSLATOR TO PARTICIPATE IN RESEARCH PROJECT

An interpreter and/or translator is ethically obligated to maintain the confidentiality of information obtained during the course of their appointed role in a research project. All information regarding the research participants and research project is subject to confidentiality.

I, _____ agree to enter into a Confidentiality/Non-Disclosure Agreement to assist the researcher <name of student> with the interpretation and/or translation of interviews/focus groups discussions. I, agree to abide by confidentiality rules and rules of professional conduct for interpreters/translators as stated as follows:

1. I shall respect all confidences received in the course of interpretation/translation and shall keep all information gained in the course of my professional duties as interpreter and/or translator strictly confidential.
2. I shall not discuss, report, publish, or comment upon a matter or case in which I serve as an interpreter/translator hereby. This includes emailing, blogging, tweeting, and posting on a website, Facebook, and other print, electronic, and social media.
3. I shall not offer an opinion to anyone regarding the anticipated outcome of the research or any other matter in which I serve as an interpreter/translator hereby.
4. I shall not disclose any communication without the prior written consent or authorisation of < name of student>.
5. I shall not make statements adverse to the positions of the research participants, or which put at issue the confidentiality of any information and/or discussions.
6. I shall render to the best of my ability a complete and accurate interpretation/ translation without altering or omitting anything that is stated.
7. I shall be unbiased and shall refrain from conduct that may give an appearance of bias.
8. I shall disclose any real or perceived conflict of interest and shall not take personal advantage, financial or otherwise, of information obtained in the course of my work.
9. I shall immediately communicate any reservations about my ability to successfully complete the assignment and shall decline any assignment I believe to be beyond my technical knowledge or linguistic ability.
10. I shall immediately report any impediment to my ability to interpret/translate accurately and completely. Examples of possible impediments include: My inability to keep up with the rate of speech of the speaker, my inability to hear, interpreter fatigue, and the use of terminology or phrases with which I am not familiar.
11. I shall store any records of interviews securely as directed by the student, and to destroy any copies of these records remaining in my possession once my involvement in the research project ends.
12. Notwithstanding the completion or non-completion of the study, this Agreement shall commence on the <insert date> and shall remain in force and effect until <insert date>, unless

replaced by another agreement concluded between the witness/interpreter/translator and the researcher superseding this Confidentiality/Non-Disclosure Agreement.

DECLARATION

I certify that I have received a copy of and have read these confidentiality rules and rules of professional conduct for interpreters/translators and agree to abide by them.

Full Name of Interpreter/Translator	
Signature	
Date	
Full Name of Researcher	
Signature	
Date	