SOP 3: The Protocol Review Process

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
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1. COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
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Checked by	Academic Manager	5 November 2021	C.E. Ford
Authorized by	Academic Dean	18 January 2022	J.O. Lotter

2. DOCUMENT HISTORY

Date	Version no	Reason for revision
March 2019	1	Development of the document
July 2021	2	Recommendations by NHREC

3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
SACAP REC	The South African College of Applied Psychology Research Ethics Committee
SOP	Standard Operating Procedure(s)
NHREC	National Health Research Ethics Council
PI	Principal Investigator
HPCSA	Health Professions Council of South Africa
SACSSP	South African Council for Social Services Professions
SRC	Scientific Review Committee

4. PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines and identify the requirements that the SACAP REC should adhere to when reviewing ethics applications and protocols (research proposals) submitted to the SACAP REC for ethical approval prior to carrying out the research.

5. SCOPE

The scope of this document covers the establishment of the procedures to follow when reviewing protocols (research proposals) and ethics applications submitted to the SACAP REC. It covers the responsibilities and procedure(s) to be followed for the protocol review process.

6. RESPONSIBILITIES

The SACAP REC Chair, Vice Chair, Administrator and SACAP REC committee members should be familiar with the procedure to follow when reviewing protocols (research proposals) for ethical clearance.

7. PROCEDURE(S)

All protocols (research proposals) must have been submitted to the College Scientific Review Committee (SRC) and approved prior to being submitted to the SACAP REC for consideration. Staff protocols (research proposals) may be submitted directly to SACAP REC for consideration. The review process will be based on a risk continuum as stipulated on risk in *SOP 17: Risk Assessment*.

7.1. Medium and High Risk:

These applications for ethical approval will follow a full review process by SACAP REC as follows:

7.1.1. The SACAP REC will only consider an ethics application if it has been submitted through the appropriate submission procedures explained.

7.1.2. Only ethics applications and research proposals which have been officially placed on the agenda for the SACAP REC will be considered.

7.1.3. The SACAP REC will review ethics applications in terms of the ethical principles that guide the work of the SACAP REC in terms of beneficence and non-maleficence, distributive justice and respect for the person as per section 2.1 of *the Department of Health (2015) Ethics in Health Research: Principles, Processes, and Structures*.

7.1.4. The SACAP REC will also during the review process consider any or all factors that may influence the scientific validity and ethical acceptability of the research.

7.1.5. The documents to be reviewed will include the completed ethics application form, research proposal, permission letters (where applicable), data collection instruments/tools, i.e. questionnaires, interview schedules, etc. These documents will be sent to SACAP REC members 10 days prior to the sitting via email from the SACAP REC Administrator.

7.1.6. For each application two members (one of which should be a primary member) with relevant expertise will be appointed.

7.1.7. All additional committee members, such as a layperson, a legal advisor, alongside the SACAP REC Chair, SACAP REC Vice-Chair, and SACAP REC Administrator will review all applications before the sitting.

7.1.8. The SACAP REC members will be required to complete the member report and present their review at the SACAP REC sitting.

7.1.9. Contributions from other SACAP REC committee members will be considered when the research proposal is discussed.

7.1.10. A decision will be made based on feedback from committee members, and an outcome communicated in writing to the student and their respective supervisor(s).

7.1.11. The decision is minuted by the SACAP REC Administrator in the REC sitting.

7.2. Negligible and Low Risk:

The SACAP REC will only consider an ethics application if it has been submitted in accordance with following submission procedures and will follow an expedited review process as follows:

7.2.1. The SACAP REC Administrator will check the application for completeness and risk level *(See SOP 17: Risk Assessment)*.

7.2.2. For negligible risk research, the application for ethical approval will be forwarded to the SACAP REC Chair who will review and provide ethical clearance, decision will be ratified during the following SACAP REC sitting.

7.2.3. For low risk research, the application for ethical approval and the associated research proposal will be submitted to two members with relevant expertise. The application will be reviewed only by the SACAP REC Administrator in relation to recommendations made by the Scientific Review Committee (SRC) in the form of a letter submitted by the Chair of the SRC for the attention of the SACAP REC Office. Should the research proposal/project need to be reviewed by the SACAP REC the following SOPs provide an outline of the process followed *(SOP 4: Proposal Applications and Decisions; and SOP 6: Preparation of Sittings and Sitting Procedures; and SOP 12: Protocol Amendment Procedures)*.

7.3. Research NOT Involving Human Participants

7.3.1. The SACAP REC will only consider an ethics application if it has been submitted through the appropriate submission procedures.

7.3.2. If the proposed research relies exclusively on publicly available information or accessible through legislation or regulation, or relies exclusively on secondary use of anonymous information (i.e. no identifiable information is generated or inferred as per risk assessment guidelines as based on the DoH Ethics Guideline, this must be noted in the application for ethical approval of research *(see Annexure A of SOP 4: Proposal Applications and Decisions)*. In this instance, the SACAP REC Chair can provide ethical clearance for the research to be carried out. The SACAP REC Chair's decision will be noted during the next SACAP REC sitting.

7.4. Key norms and standards to consider during the review process

7.4.1. **Relevance and value:** The SACAP REC will consider the application for ethical approval of research in terms of the research being relevant and responsive to the needs of the people in South Africa whether it be individuals, groups or

communities. The SACAP REC members will review health-research related applications and consider the anticipated contribution to knowledge, the potential contribution of the research to diagnostic or therapeutic intervention, the development of an intervention; or testing an hypothesis that could generate important knowledge about human functioning even if there is no immediate effect on people and communities, and how the findings will translate into products, interventions, processes, and services which may improve the quality of life, health, and well-being of people and communities in South Africa either directly or indirectly. Further to this, the SACAP REC members will consider the potential value of the dissemination of the results, the practical significance thereof, and impact of the results. The latter is informed by the view that if a study can be shown to have no significance or benefit to people and communities who would be involved in the research the research would be deemed ethically unjustifiable.

7.4.2. **Scientific merit and integrity:** In relation to the proposed study, SACAP REC members will consider the study design and methodology regardless of the discipline. It is critical that members are convinced that a proposed study has provided enough scientific evidence that the study will not cause unnecessary risks and burden to participants. A poorly designed study that includes incorrect application of quantitative and qualitative research methods and analysis takes away from any benefit the study might have in the form of useful knowledge gained from the study. A well-designed study would involve a clear understanding of and application of suitable research methods, based on established scientific principles of research design and analysis, to address the aims and objectives of the study. Furthermore, the feasibility of the study will be considered in terms of whether the study can be executed. Where a study has too few participants which could have implications for identifiable information generated or inferred from the findings, when the interviewee is known in another context and the implications this has in the form of conflict of interest, poorly formulated or leading interview questions, or proposing small sample sizes in quantitative projects may impact on the ability of the study to generate valid scientific knowledge, and this would be deemed ethically unjustifiable research. The SACAP REC members will read the research approach of the research proposal from the perspective of determining whether the researcher(s) have identified, evaluated and described risks and benefits for the participants, including what strategies or steps will be in place to minimize/manage any risks, consider whether the risk/benefit ratio acceptable for proceeding with the research, and whether any potential harm, exploitation, unwarranted exclusion from society or being ostracised by neighbours/friends/family/significant reference or peer group might be incurred on participants due to participating in a research study. A study without scientific merit and integrity cannot generate the intended knowledge, nor produce any benefit to people or communities as the exposure of respondents and participants to burdens and risks would outweigh the any benefit of the study, and this be deemed ethically unjustifiable research.

7.4.3. **In relation to the researcher(s)/students/supervisors:** SACAP REC members will evaluate the suitability of the researcher(s) to execute the study in terms of their experience, suitable qualifications, training received, and supervision from an expert or seasoned researcher and where necessary the intervention of other more qualified and experienced assistants, such as an HPCSA registered psychologist, SACSSP registered Social Worker or any other

qualified person to act as a research consultant to assist with research-related matters, i.e. data collection, methods of analysis and conceptualisation of projects. Where necessary, the researcher(s) CV will be considered to determine the suitability and experience of the researcher to perform certain research-related activities within the scope of the research project. The SACAP REC may request documentation to confirm that the researcher(s) have the necessary knowledge, skills or level of competence needed to carry out the research procedures specified in the protocol.

7.4.4. **Role-player engagement and request for gatekeeper/organisational permission for access to data or participants:** The SACAP REC will evaluate the manner in which researchers intend to approach key role-players in the research project, including those who serve as gatekeepers for access to data or participants. In this instance, requesting permission to access data or participants by way of approaching a community or people of a particular organization, gathering, firm or any other establishment should be visible through appropriate permission letters. The ethical nature of a study is challenged where researchers do not respect the persons, property, community, environment, establishment and/or resources at their disposal when conducting research resulting in trespassing. Role-player engagement may also be addressed by the researcher in terms of awareness-raising initiatives where these potentially increase acceptability of the research by key role players, improve the quality and rigour of the research, harness role player expertise, and offset power differentials where applicable.

7.4.5. **Favourable risk-benefit ratio:** SACAP REC members will review a risk-benefit analysis provided in the research proposal to determine whether at minimum it includes a desirable ratio or favourable risk-benefit ratio where the potential risk of harm to a participant is outweighed by the likelihood of benefit, for participants or to society, from the knowledge to be gained from the research. In other words, the likelihood of benefit should outweigh the anticipated risk of harm to participants. This can only be achieved, especially in health-related research when the SACAP REC committee is satisfied that the potential risk to individual subjects is minimised. In this regard, risk minimisation measures to be followed should be indicated in the protocol, along with the potential benefits to individual participants and society is proportionate to or outweighs the risks. Risks to participants are reasonable in relation to the anticipated benefits to participants and/or community as well as the importance of the knowledge that may be reasonably expected from the study. The requirement for a favourable risk-benefit ratio encapsulates the principles of non-maleficence and beneficence as fundamental ethical values of all research. The SACAP REC members will therefore only consider the risks and benefits that may result from the research itself as it is presented and not the long-term effect of the research when the knowledge is applied. Long-term consideration of the effect of the study may be considered in terms of the impact of procedures and methods applied to obtain the data. A phased approach should be adopted for a study where participants who might face undue risk or harm have been considered after careful review of the application and acceptable justification that demonstrates that the anticipated importance and value of the research for society can be proven. However, such participants should under normal circumstances not be included in a study even if they represent a category of persons that may benefit from the research.

7.4.6. **Fair selection of participants:** SACAP REC members will consider the just and fair way in which selection, recruitment, exclusion, and the inclusion of participants in the research project has been envisioned. In particular, the sample selection criteria that will be followed will be scrutinised to determine if any persons were excluded unreasonably/unfairly or unfairly targeted for research purposes, such as on the grounds of race, age, sex, sexual orientation, disability, education, religious belief, pregnancy, marital status, ethnic or social origin, conscience, belief or language as per the South African Constitution. SACAP REC members will be particularly sensitive and cognisant of the inclusion of vulnerable populations, such as children, prisoners, pregnant women, intellectually impaired persons or economically or educationally disadvantaged persons in research proposals/projects. In particular, the SACAP REC will evaluate if the involvement of vulnerable persons in the research has been adequately justified and appropriate safeguards have been put in place to minimise risk of any harm to protect the rights and welfare of vulnerable participants. Sampling techniques selected need to be based on scientific grounds and not solely based on convenience sampling, or recruitment of vulnerable participants who may feel coerced to participate or have compromised ability to consent to participate in research. To this end, participant selection should include a clear description of who will be included in the study by means of inclusion and exclusion criteria as well as the sampling strategy that will be used to recruit the individual participants and/or communities to include. Groups or individuals should not be excluded from the opportunity to participate in research without valid scientific reasons or a clear justification that their participation might lead to actual, potential or perceived harm.

7.4.7. **Informed consent:** The general principle of informed consent entails that participation in research must be voluntary and based on informed choice. Both these principles should be evident in the informed consent process, which must take place before the research can commence and be reiterated during the course of the study as part of the researchers' commitment to an ongoing consent process. The purpose of informed consent is to ensure that individuals control whether or not they participate in any form of research whether it be clinical interventions, interviews, questionnaire completion or any other form of research, and only to participate in research that is consistent with their values, interests, and preferences. In order for a participant to provide informed consent, they must be accurately informed of the purpose, nature, methods, risks, benefits of a study, the right to decide whether to participate in a study, as well as the right to withdraw from a study at any time. Furthermore, it must be clear to the committee that the participant is able to make a voluntary and un-coerced decision whether to participate or not. Informed consent reflects the researcher's respect for persons and their autonomous decisions. The procedure through which informed consent is obtained as described in *SOP 13: Informed Consent*.

7.4.8. **Ongoing respect for enrolled participants:** Ongoing respect for the protection of human rights and social justice needs to be observed throughout a study which includes from the time participants are approached to obtain voluntary consent to participate in the study, during their participation and even after the completion of the study. This respect, firstly mirrors how well privacy and confidentiality of participation is managed; secondly, respect includes permitting participants to change their mind and withdraw from the study;

thirdly, that any additional information that may have an effect on the participation of the individual be shared with them at the onset and over the course of the duration of the study; and fourthly, the welfare of the participant should be monitored throughout the study irrespective if it is a clinical study or not, including not exposing participants to dangerous situations and lastly to recognise the participants contribution in the study through their contribution to the study by providing feedback about the study. Therefore, the member will consider the extent to which the researcher is able to manage respect for the participant and to protect the constitutional rights of the participants to privacy and confidentiality as these principles should be addressed and explained in the proposal as well as the way in which the researcher will achieve this. Privacy is concerned with who has access to personal information and records about the participant which includes clinical healthcare records. Confidentiality, on the other hand, deals with ensuring that appropriate measures will be implemented to prevent disclosure of information that might identify the participant either during the course of the research or afterward. The members will be considering the way in which the researcher maintains confidentiality by respecting the rights to choose to whom, and what personal information is disclosed, the limits to confidentiality and how the results will be published as well as the ways in which confidentiality will be maintained.

7.4.9. **Ongoing respect for communities:** SACAP REC members will be sensitive to and cognizant of the respect that researchers should be showing towards participating communities or individuals from communities in a research project. The inclusion of such communities during the development of a research project may be meaningful especially where the impact of the research on the community may be experienced by all. The researcher needs to demonstrate respect for community structures, leaders, ward councillors and other key role-players who are the gatekeepers of the participants the researcher wants to access. Respect should be shown in the attitude in which these gatekeepers are approached to allow access to a particular community and the respect shown for environmental, social, cultural, traditional practices and rituals within these communities. Respect from the researcher should also reflect in the way in which the community is protected by the principles of anonymity and confidentiality during and after their participation. The member will also consider the way in which interaction with the community will be maintained and appropriate ways feedback of results stemming from the study can be given.

7.4.10. **Researcher competence and expertise:** The committee will consider the suitability and technical competence of the researcher(s) to carry out the research. In particular, the principal investigator (PI) or lead researcher is primarily responsible for ensuring the safety and well-being of the participants, scientific integrity of the protocol and responsible implementation of the protocol. In instances where students are supervised, the supervisor considers the responsible person who takes the responsibility of the PI as explained. Competence will be considered in terms of academic qualification, credentials, scientific and technical competence. It also includes research competence which can be assessed through education, knowledge, certification, and experience. Competence and expertise also include dissemination of results whether positive or negative in a timely, accessible,

responsible and competent manner which will include reporting back to participants.

8. REFERENCE DOCUMENTS

- Stellenbosch University. (2015, May). *HREC standard operating procedures (SOPs) and guidelines* (v4.2).
- Emanuel, E.J., Wendler, D., & Grady, C., (2000). What makes clinical research ethical? *Journal of the American Medical Association, 283(*30), 2701 – 2711.
- Department of Health. (2015). *Ethics in health research: Principles, processes and structures* (2nd ed.).