SOP 14: Adverse Events, Serious Adverse Events and Unanticipated Problems

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
Title	SOP 14: Adverse Events, Serious Adverse Events and Unanticipated Problems
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Pages	7

1. COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled for SACAP by	Dr Malesa Kgashane	6 August 2021	
Amended for SACAP by	SACAP 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
Amended for SACAP by	Dr Diana De Sousa: SACAP REC Chair	5 August 2023	D.S. De Sousa

2. DOCUMENT HISTORY

Date	Version no	Reason for revision
July 2021	1	Development of the document
August 2023	2	Refinement of procedures pertaining to timeframes.

3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
SACAP REC	The South African College of Applied Psychology Research Ethics Committee
NHREC	National Health Research Ethics Council
SOP	Standard Operating Procedure(s)
ED	**Ethical Difficulties** Refers to issues that made it hard or impossible for the researcher/fieldwork to obtain verbal or written consent from potential research participants, e.g., unwillingness to sign a consent form, being suspicious of research, demand for incentives (money or other material items), capacity to give consent and insistence on providing collective rather than individual consent.

IN	**Incident** An unanticipated occurrence that arises with participants or researchers during research has no direct link to the research. It could have unexpected and often negative consequences for the health, privacy, and safety of the participants involved in the research, or the researchers involved and or SACAP as the institution.
UP	**Unanticipated Problems** Refers to incidents that are unexpected or if the occurrences were anticipated the researcher could not anticipate the extent of or provide full details about the expected incidents when applying for ethics clearance.
AE	**Adverse Events** Refers to any untoward medical or psychological occurrence in a human research participant, including any abnormal laboratory finding, symptom, or disease, and which does not necessarily have a causal relationship with the research, or any risk associated with the research. Any event that can affect research participants or data integrity negatively with the potential to impact negatively on members of the research team, or on the project as a whole.
SAE	**Serious Adverse Event** Refers firstly to any situation that arose during data gathering which relates to the participant and has resulted in death, life-threatening consequences required hospitalization or prolonged hospitalization of the participant or resulted in persistent or significant disability/incapacity of the participant. Specific to health research, this definition also applies where a life-threatening situation might have arisen during data gathering which has resulted in serious injury, hospitalization, or disability of the researcher.

4. PURPOSE OF THE SOP

The purpose of this SOP is to provide guidelines for the timely reporting of adverse events, serious adverse events, and unanticipated problems that might place the participant(s) or researcher at risk.

5. SCOPE

The scope of this document covers the establishment of the procedures to follow for the reporting of any adverse event, serious adverse event, and unanticipated problems arising during the study. This document also covers the procedures to follow for the reporting of these occurrences. It covers the responsibilities and procedure(s) to be followed when these events and problems occur.

6. RESPONSIBILITIES

All SACAP REC members, researchers with ethics approval, and the SACAP REC Administrator should be aware of the procedure during the reporting of serious adverse events and unanticipated problems.

7. PROCEDURE(S)

7.1. Any adverse event, serious adverse event, or unanticipated problems should be reported to the SACAP REC within 24 hours of the incident.

7.2. Following this initial report, the SACAP REC should be informed in writing by completing the Adverse Event, Serious Adverse Event, and Unanticipated Problems Report Form within 72 hours of the incident (*Annexure A of SOP 14: Adverse Events, Serious Adverse Events, and Unanticipated Problems*) that can be found or requested from the REC Administrator.

7.3. The report is then submitted electronically to the SACAP REC Administrator.

7.4. The report should include as much detailed information as possible including the following:

7.4.1. Nature of the incident that is being reported.

7.4.2. When and where the incident took place.

7.4.3. Who was present during the incident (researchers, fieldworkers, participants, etc.).

7.4.4. Context in which the incident happened.

7.4.5. Action that was taken by the researcher(s).

7.4.6. Outcome of the action taken; and

7.4.7. Signature of the researcher and date of submission.

7.5. The SACP REC Administrator must alert the SACAP REC Chair of the report. This report should form part of the agenda in the next scheduled REC meeting.

7.6. If the report falls in between meetings and is urgent, a special SACAP REC meeting can be called to discuss the contents of the report.

7.7. The report should be placed on the agenda together with the latest version of the proposal, a list of any amendments made, and the original application and associated documentation.

7.8. The original SACAP REC reviewers should re-familiarize themselves with the initial and updated submissions to provide context to the report that has been submitted.

7.9. All SACAP REC committee members receive the report and documentation in a special meeting convened to enable all SACAP members to study the report.

7.10. Should the researcher be concerned about any events that may have a serious impact on the study or of the opinion that related event(s) may have an effect on the participants, staff, or data integrity, the researcher should report such concerns to SACAP REC.

7.11. Should the SACAP REC deem it necessary to engage with the researcher to clarify matters related to the report, the committee may arrange such an appointment during the committee meeting or afterward.

7.12. The SACAP REC committee decides on the most appropriate remedial action which may be any of the following:

7.12.1. Suspension or discontinuation of the project depending on the nature of the risk to participants and/or researcher.

7.12.2. Suspension of enrolment of new research participants.

7.12.3. Suspension of any further engagement with research participants.

7.12.4. Modification to the informed consent documents to include additional information not previously included that address newly identified risks to new participants.

7.12.5. Provision of additional information about newly identified risks to currently enrolled research participants and a requirement for such participants to sign an informed consent addendum and/or update.

7.12.6. Advising on the way forward to minimise continuous risk; and

7.12.7. Protocol/research proposal revision/amendments, including possible modification of eligibility criteria to mitigate the newly identified risks.

7.13. In cases where potential legal, reputational, financial, and personal harm may arise due to an adverse event, the SACAP REC will report such cases to the Academic Head of the institution (Academic Dean) who will table this at College Management and Leadership for noting and/or deliberation in the event further action is required.

7.14. All adverse cases, decisions, and processes must be included in the annual report to the NHREC.

8. REFERENCE DOCUMENTS

- Department of Health. (2015). *Ethics in health research: Principles, processes, and structures* (2nd ed.).
- Stellenbosch University. (2015, May). *HREC standard operating procedures (SOPs) and guideline*s (v4.2).
- University of the Witwatersrand (2022, November). *Human Research Ethics Committee (Non-Medical) Serious Adverse Event (SAE) Reporting Form*.

ANNEXURE A:

SACAP RESEARCH ETHICS COMMITTEE

ADVERSE EVENTS, SERIOUS ADVERSE EVENTS, AND UNANTICIPATED OCCURRENCES REPORT FORM

The Research Ethics Committee is required to monitor research projects which it has approved. Please use this form to report incidents that may impact the SACAP REC's continued approval of a research project.

Note: An unanticipated occurrence that arises with participants or researchers during research that has no direct link to the research. It could have unexpected and often negative consequences for the health, privacy, and safety of the participants involved in the research, or the researchers and/or institutions involved.

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The SACAP REC Chair will complete Section D.

SECTION A: GENERAL INFORMATION						
1. Researcher Details						
Surname		**Initials**		**Title**		
Faculty and Degree						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
2. Details of approved research						
Title						
Ethics Approval Number						
Approval date		**Expiry date**				
Last submission of a monitoring report		**Date:**				
SECTION B: INCIDENT REPORT						
Please describe the progress to date of the project (not more than 500 words):						

Please describe the nature of the incident (adverse and/or unanticipated event) you personally observed in detail (please ensure that you respond to what, where, who was involved, how, and when of the incident):
Did anyone sustain harm or injury in the incident? If YES, please give the details of this person(s)and the nature of the harmful injury.
Please describe the cause of the adverse and/or unanticipated event/s
Please describe the action that has been taken to date in detail to contain the incident (e.g., medical advice sought, psychological debriefing, data collection suspended, etc.)
Was the event/s a result of actions taken as per the approved research proposal? Please give reasons to explain your answer.
Please indicate a possible strategy/action plan for correcting the incident:
Please indicate a possible strategy/action plan for ensuring that it will not occur again:

	Yes	**No**	**NA**
Will this incident require that the proposal will have to be changed? Please explain your answer. **If yes, please ensure that an amendment request is submitted to the SACAP REC Office (rec@sacap.edu.za) within 2-3 working days of the incident occurring.**			

SECTION C: SIGNATURE			
Before signing remember to attach any additional documents relevant to this form, such as additional pages of information or copies of relevant approvals.			
By signing this document, I certify that the information provided is accurate and complete.			
Signature by the researcher		**Date**	

Signature by the researcher supervisor			
SECTION D (for office use only):			
REC Office report	**Yes**	**No**	**NA**
Has the incident been satisfactorily reported?			
Has the incident been satisfactorily addressed?			
If yes, please explain how the incident was managed with the researcher(s) the research supervisor (s), and the research participants to prevent a similar future incident from occurring.			

REC Chairperson	**Signature**	**Date**