SOP 8: Annual Progress and Monitoring Reports

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
Title	SOP 8: Annual Progress and Monitoring Reports
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1. COMPILATION AND AUTHORIZATION

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	11 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	Revision of active and passive monitoring forms and procedures

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 purpose of this SOP is to provide guidelines on the annual progress and monitoring of research reports/projects.

5. SCOPE

The SACAP REC is required to request regular, at least annual, reports from principal investigators (NHREC, 2015). The scope of this document covers the establishment of the procedures to follow for the annual progress and monitoring reports for a continuous review process.

6. RESPONSIBILITIES

The SACAP REC Chair, Vice Chair, Administrator and REC committee members have the responsibility to ensure that the conduct of all the approved research projects is monitored on an ongoing basis. The frequency and type of monitoring should reflect the degree of risk to participants in the research project. Routine monitoring involves the regular review of study progress reports but sometimes may include additional monitoring of a research project in the form of a site audit where applicable. The main objective of a site audit is to ensure compliance with the approved research proposal and to ensure adequate protection of the research participants.

7. PROCEDURE(S)

7.1. **Active Monitoring.**

The following procedures and/or principles are applicable to site audits:

7.1.1. The focus of a site audit is to ensure that the research project is being conducted in an ethical manner and that the research participants' interests are fully recognized, represented, and protected; (*See Annexure A of SOP 8: Researcher Annual Monitoring Form*).

7.1.2. The SACAP REC Chair, or a person appointed by the REC, assumes responsibility for the conduct of a site audit, directs the process, and acts as a facilitator.

7.1.3. Parties involved in a site audit include the researcher, the research team, the REC, the REC Chair, and the auditor/audit team.

7.1.4. The REC has the authority to audit any research site, especially sites of approved high-risk research, sites from which complaints have been received (whether by a participant, sponsor, or a third party), and research sites at which it is suspected that the procedures approved by the REC are not being followed.

7.1.5. A notification of research sites for proposed audits will be tabled at a REC sitting before the commencement of those site audits.

7.1.6. The researcher will be given at least two weeks' notice of a site audit to ensure their active participation and to protect their right to due process.

7.1.7. The audit team will examine the research project's procedures and conduct to determine whether it complies with the ethical standards and regulatory requirements governing the specific project.

7.1.8. In the case of audits in response to a complaint, the audit team will be supplied with an audit brief, which outlines the complaint and indicates specific focus areas for the audit.

7.1.9. Interviews may be conducted with the researcher and site personnel.

7.1.10. Depending on the nature and timing of the site audit, the audit team may contact research participants, observe the informed consent process, or require a third party to observe the informed consent process or research procedures.

7.1.11. Some or all the following documents may be examined by the audit team during the site audit, depending on the nature of the audit and the nature of the study:

7.1.11.1. Certificate of REC approval and approval of any proposal amendments or other changes.

7.1.11.2. Copy of the REC approved the proposal and any amendments.

7.1.11.3. Progress report/s to REC.

7.1.11.4. Copies of data collection sheets, questionnaires, and informed consent document.

7.1.11.5. Signed consent documents.

7.1.11.6. Any advertisement used for participant recruitment.

7.1.11.7. Correspondence and communication with funders, and other authorities.

7.1.11.8. Laboratory certification (including updates); and/or

7.1.11.9. Copies of serious adverse event reports.

7.1.12 The audit team will compile an audit report, which is submitted to the next REC sitting for discussion and approval. The researcher will also receive a copy of the audit report.

7.1.13 The researcher will be requested to respond formally in writing to the audit report and address each point. The researcher's report should also include a corrective action plan, if appropriate.

7.1.14 The REC may invite the researcher to the REC sitting to discuss any findings of the site audit, including findings of non-compliance and/or misconduct; and

7.1.15 The REC should decide either by consensus or by vote to:

7.1.15.1. Accept the audit findings and the researcher's written response as acceptable with no cause for further action. A final letter will be sent to the researcher, briefly summarising the outcome, and declaring the matter satisfactorily resolved.

7.1.15.2. Request the researcher to provide additional information, or take some other form of corrective action, which may even involve a suspension of approval of the research study involved; or

7.1.15.3. Act in accordance with *SOP 14: Adverse Events, Serious Adverse Events, and Unanticipated Problems*.

7.2. **Passive Monitoring**.

The following procedures apply to the routine continued review of research projects:

7.2.1 Routine continued review is conducted annually unless stipulated otherwise in the initial approval letter.

7.2.2 Based on the risk level of the study, researcher(s) may be required to submit a progress report to the SACAP REC office, so that the progress report can be reviewed, and the project re-approved before the expiry date provided on the letter of ethical approval. No research may continue without submission of the progress report process and its re-approval. (*See Annexure B of SOP 8: Researcher Annual Monitoring Form*).

7.2.3 All the submitted progress reports will be included in the agenda for the next REC sitting for review, discussion, and approval; and

7.2.4 The SACAP REC has the authority to impose restrictions on, suspend, or terminate any study in which the researcher fails to comply with the review process, or where such actions are deemed appropriate and justified by a fully convened REC sitting.

7.2.5 The following information must be recorded in the progress report:

7.2.5.1 Name of the primary researcher.

7.2.5.2 Project title.

7.2.5.3 SACAP Research Ethics reference number.

7.2.5.4 Status of data collection.

7.2.5.5 Status of the research procedures as per the approved project proposal.

7.2.5.6 Number of research participant withdrawals of consent.
7.2.5.7 Risk and unexpected ethical issue management.
7.2.5.8 Short summary of any serious adverse events; and
7.2.5.9 Any other relevant information, especially information about risks associated with the study.

7.3. SACAP REC HYBRID MODEL OF PASSIVE AND ACTIVE MONITORING

Within the scope of SACAP's formal qualifications, research projects are conducted with rigorous and well-supported supervision to uphold ethical research practices. SACAP employs a comprehensive support framework, involving both internal and external staff overseeing postgraduate and professional qualifications. The SACAP REC utilizes a hybrid monitoring approach that combines active and passive methods to effectively ensure ethical oversight. This approach is tailored to the specific research nature, risk level, and available resources within the SACAP context.

7.3.1 Oversight and Alignment

The Institutional Head of Postgraduate and Professional Programme Management oversees research processes to ensure consistency and alignment across various campuses. A multi-channel approach to research ethics training for student researchers and their supervisors is employed. This involves training supervisors in research ethics and ethics review procedures. Webinars on research ethics are hosted as part of the Postgraduate Research Seminar Series. Additionally, a repository of ethical documentation is accessible to students and supervisors through the Postgraduate Research Hub dedicated to honours and master's level students. This Hub is managed collaboratively by the SACAP REC and the Head of Postgraduate and Professional Programme Management. Campus-specific program coordinators further enhance support to students engaged in research activities.

7.3.2 Ongoing Active Supervision and Reporting

Student researchers are paired with dedicated research supervisors selected for their expertise, including research ethics. This supervision spans from the proposal stage to dissemination, prioritizing participant welfare and research credibility. Throughout the research project, research supervisors are required to submit a digital supervision progress report form after each supervision session with the students they oversee. This form is based on the Annual Active Monitoring Report Form outlined in SOP 8. The completed form is electronically submitted to the Head of Postgraduate and Professional Programme Management, who collaborates with the SACAP REC on ethical matters. The initial active monitoring and ethical review conducted by research supervisors are further enhanced by the evaluation of research proposals by the Scientific Review Committee, overseen by the Head of Postgraduate and Professional Programme Management in consultation with the SACAP REC. This dual review approach ensures that research design adheres to ethical standards right from the outset.

7.3.3 Ongoing Passive Monitoring

Upon obtaining ethical clearance through SACAP REC deliberations, the committee transitions to an ongoing passive monitoring approach. Student researchers, under the guidance of their designated research supervisors, are entrusted with adhering to approved protocols and ethical guidelines. The SACAP REC relies on self-reported updates from these students regarding their progress and any emerging ethical concerns.

7.3.4 Regular Communication and Reporting

To maintain ethical oversight, the SACAP REC maintains regular communication with the Head of Postgraduate and Professional Programme Management, who oversees campus-specific program coordinators and research supervisors. This interaction involves periodic check-ins and the review of student research progress through digital MS progress report forms. These forms are derived from the Annual Passive Monitoring and Progress Report Form detailed in SOP 8. Both students and supervisors independently complete these digital forms, which are then submitted electronically to campus-specific program coordinators overseen by the Head of Postgraduate and Professional Programme Management. Subsequently, a summarized report is compiled by the Head of Postgraduate and Professional Programme Management for assessment by the SACAP REC. This process serves as an alert mechanism, triggering a site visit by the committee if circumstances necessitate to ensure

research adherence to approved protocols and ethical guidelines. As of now, no instances warranting a site visit due to raised ethical concerns have been reported.

7.3.5 High-Risk Projects and Ethical Safeguards

The summary reports play a crucial role in overseeing high-risk MSocSci research projects involving vulnerable populations. They uphold research's ethical standards and safeguard participants' rights and well-being. If researchers encounter ethical concerns or unanticipated challenges, the SACAP REC can transition into an active monitoring mode, responding promptly through additional reviews, discussions, or interventions. This ensures that research remains ethically sound and aligned with the highest standards throughout its lifecycle.

8 REFERENCE DOCUMENTS

- Stellenbosch University. (2015, May). *HREC standard operating procedures (SOPs) and guidelines* (v4.2).
- Department of Health. (2015). *Ethics in health research: Principles, processes, and structures* (2nd ed.)
- Tshwane University of Technology. (2012, June). *Research ethics committee standard operating procedures and guidelines*
- University of Johannesburg (2023, April). *Annual active monitoring report form*.
- University of Johannesburg (2023, April). *Passive monitoring report form*.
- University of the Witwatersrand (2022, November). *Human Research Ethics Committee (Non-Medical), progress report.*

ANNEXURE A:

SACAP RESEARCH ETHICS COMMITTEE

ANNUAL ACTIVE MONITORING REPORT FORM

- The purpose of this form is for SACAP REC members (as reviewers) to monitor the progress of selected research projects onsite and report to the SACAP REC
- Reviewers should submit the completed active monitoring reports to **Kyle Young at the SACAP REC office** at rec@sacap.edu.za

Student or Researcher's Name		**Student/Researcher's Staff Number**	
Supervisor Name (If applicable)		**Co-Supervisor Name (If applicable)**	
Department/Centre			
Research Proposal Title			
Original Ethics Clearance Number		**First Clearance Date**	
Last Renewal Date (if applicable)		**Number of Renewals**	

Instructions to REC members conducting the active monitoring:

- Please complete all sections 1-11 below and comment on your observations.

1. Stage of Ongoing Research

1.1. Data Collection Ongoing	☐	1.2. Data Collection Complete	☐
1.3. Data Analysis Ongoing	☐	1.4. Data Analysis Complete	☐
1.5. Research Report/Dissertation/ Thesis Writing	☐	1.6. Research Report/ Dissertation/ Thesis Writing Complete	☐

2. Research progress observed and/or reported by the researcher: (Please provide an overall summary of the research progress as reported by the researcher from the last clearance approval or renewal.)

Click here to enter your explanation.

3. Evidence of informed consent of participants, parents, or guardians and assent of minors where applicable

Have there been any challenges in obtaining the consent of participants to provide data in the period covered by this report?

3.1. Yes ☐ 3.2. No ☐

If yes, please provide details below, and indicate how the consent/assent was documented:

Click here to enter your explanation.

4. Evidence of consistency or changes in research methods, data collection instruments, and storage methods

Have there been any changes in research methods, data collection instruments, and/or storage in the period covered by this report?

4.1. Yes ☐ 4.2. No ☐

If yes, please provide details below, and indicate how they were dealt with:
Click here to enter your explanation.

5. Documentary evidence of Reportable Events/Deviations, etc.

Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.**

5.1 Serious Adverse Event(s) (SAEs)	☐	5.2 Non-serious Adverse Event(s)	☐
5.3 Related AE(s)	☐	5.4 Unrelated AE(s)	☐
5.5 Anticipated AE(s)	☐	5.6 Unanticipated AE(s)	☐
5.7 Proposal Deviation	☐	5.8 Proposal Non-compliance	☐

NB 1: Check whether the researcher reported any SAEs and related AEs within 48 hours of discovery during the research period. ……

NB 2: Check whether any non-serious AEs, related AEs, all deviations from the proposal, and non-compliances were reported within 5 working days of discovery during the research period

6. **Evidence of voluntary withdrawal of participants where applicable?**

Check whether there has been any withdrawal of participants in the period covered by this report.

6.1 Yes ☐ 6.2 No ☐

If yes, please explain the details below, and indicate how they were handled:
Click here to enter your explanation.

7. Evidence of informed consent of participants, parents, or guardians and assent of minors where applicable

Have there been any challenges in obtaining the consent of participants and the assent of minors (where applicable) to provide data in the period covered by this report?

6.3 Yes ☐ 6.4 No ☐

If yes, please provide details below, and indicate how the consent/assent was documented:
Click here to enter your explanation.

8. Evidence of consistency and/or changes in data collection and/or storage methods

Has there been any changes in research methods, data collection instruments, and/or storage in the period covered by this report?

6.5 Yes ☐ 6.6 No ☐

If yes, please provide details below, and indicate how they were dealt with:
Click here to enter your explanation.

9. Documentary evidence of Reportable Events/Deviations, etc.

Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.**

9.1 Serious Adverse Event(s) (SAEs)	☐	9.2 Non-serious Adverse Event(s)	☐
9.3 Related AE(s)	☐	9.4 Unrelated AE(s)	☐
9.5 Anticipated AE(s)	☐	9.6 Unanticipated AE(s)	☐
9.7 Proposal Deviation	☐	9.8 Proposal Non-compliance	☐

NB 1: If relevant check whether the researcher reports SAEs and related AEs within **24 hours** of discovery during the research period. ……

NB 2: If relevant Indicate whether any non-serious AEs, related AEs, all deviations from the proposal, and non-compliances were reported in adverse events, serious adverse events, and unanticipated occurrences report form within **72 hours** of discovery during the research period.
……..

11.1 Yes ☐ 11.2 No ☐

If yes, please explain the nature of the conflict(s) below, and indicate how they were addressed by the researcher:

Click here to enter your explanation.

REC Member's Signature		**Researcher's Signature**	
Date (DD/MM/YYYY)		**Date (DD/MM/YYYY)**	

For office use:

Date the progress report was received	
Comments from SACAP REC chair	
Signature of SACAP REC chair	
Date Approved	

ANNEXURE B:

SACAP RESEARCH ETHICS COMMITTEE

ANNUAL PASSIVE MONITORING AND PROGRESS REPORT FORM

Ethics approval is valid for one year only. A condition of receiving a protocol number from the SACAP REC (Research and Ethics Committee) is that a progress report is submitted at regular intervals throughout the duration of the ethical clearance as specified in the letter of ethical approval. A progress report is an application for renewal of ethics approval and must be submitted annually, well before the ethics approval expiry date, so that the progress report can be reviewed, and the project re-approved **before** the expiry date provided on the letter of ethical approval. **No research may continue without submission of the progress report process and its re-approval.**

The purpose of this form is for researchers to report to the SACAP REC on the progress of their research at appropriate intervals based on the risk level of the research project as outlined below:

- **For negligible, minimal, and low-risk studies a progress report needs to be submitted 12 months after the expiry date listed on the SACAP REC letter of ethical approval.**
- **For medium and high-risk studies, a progress report needs to be submitted twice - at due 6 months and 12 months from the date listed on the SACAP REC letter of ethical approval.**

It is important to note this requirement. Failure to submit progress reports while data collection from human participants is still ongoing will result in the project being considered in violation of its ethics clearance, and the clearance will be suspended. Please fill out the progress report form and send it via email to **Kyle Young at the SACAP REC office** at rec@sacap.edu.za at the appropriate intervals based on the risk level of the research project as outlined above.

Student or Staff Member's Name		**Student/Staff Member's Number**	
Supervisor Name (If applicable)		**Co-Supervisor Name (If applicable)**	
Department/Centre/ Division			
Research Proposal Title			
Original Ethics Clearance Number		**First Clearance Date**	
Last Renewal Date (if applicable)		**Number of Renewals**	

Instructions:

- Please complete all sections 1-5 below and provide explanations or clarifications where required.

1. Stage of Ongoing Research (*Mark with an X inside the box***)**			
1.7. Data Collection Ongoing		1.8. Data Collection Complete	
1.9. Data Analysis Ongoing		1.10. Data Analysis Complete	
1.11. Research Report/Dissertation/ Thesis Writing Ongoing		1.12. Research Report/Dissertation/ Thesis Writing Complete	

2. Research Progress: (Please provide an overall summary of the research progress from the last clearance approval or renewal date to date whichever is applicable). Please state if you have finished collecting your data from human participants.
Click here to enter your progress report.

5. Participant recruitment, informed consent of participants, and assent of minors (where applicable)
Have there been any challenges in obtaining the consent of participants to provide data in the period covered by this report?
5.1. Yes ☐ 5.2. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.
6. Changes in data collection or storage methods
Have there been any changes in data collection methods or storage in the period covered by this report?
6.1. Yes ☐ 6.2. No ☐ If yes, please explain the details below, and indicate how they were dealt with: Click here to enter your explanation.
5. Withdrawal of participants
Has there been any withdrawal of participants in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.
6. Ethical consideration and any potential ethics issues encountered.
Have there been any ethical issues and how were these managed/resolved in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.
7. Unanticipated problems
Have there been any unanticipated problems how were these managed/resolved in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.
8. Adverse events

Have there been any adverse events and how were these managed/resolved in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.

9. Serious adverse events
Have there been any serious adverse and how were these managed/resolved in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and indicate how they were handled: Click here to enter your explanation.

10. Publications/Dissemination of results
Have there been publications/disseminations in the period covered by this report?
a. Yes ☐ b. No ☐ If yes, please explain the details below, and provide copies of **published abstracts and/or papers may be submitted as attachments.** Click here to enter your explanation.

11. Attachments	
Please indicate if you have attached any of the following documentation. Include documents only if relevant to your progress report application**.**	
Current informed consent documents	
Published articles or abstracts	
Literature (a summary of any recent literature that may be relevant to the research)	

Supervisor/Researcher Signature		**Student Signature (If applicable)**	
Date (DD/MM/YYYY)		**Date (DD/MM/YYYY)**	

For office use:

Date the progress report was received	
Comments from SACAP REC chair	
Signature of SACAP REC chair	
Date Approved	