

SOP 12: Protocol Amendment Procedures

The South African College of Applied Psychology Research Ethics Committee	
Title	SOP 12: Protocol Amendment Procedures
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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

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 purpose of this SOP is to provide guidelines on the amendments to protocols that may be required during a research proposal/project.

5. SCOPE

The scope of this document covers the establishment of the procedures to follow when amendments to a protocol is required. It covers the responsibilities and procedure(s) to be followed for these processes.

6. RESPONSIBILITIES

All SACAP REC members, researchers and students with ethics approval, as well as the SACAP REC Administrator, should be aware of the procedure during the continuous review and recertification process.

7. PROCEDURE(S)

- 7.1. During the duration of a research project it may be necessary to amend the original protocol in order for the study to proceed. In such instances, the SACAP REC must review and approve all protocol amendments to any application, which originally had ethics approval from the committee before implementation of the new protocol may take effect.
- 7.2. Amendments to a protocol are considered planned changes that should be implemented by the researcher to an already approved study protocol. These amendments can be classified as minor amendments or major amendments (substantive).
 - 7.2.1. **Minor Amendments:** Minor amendments do not change the risk benefit profile of the study in any way. These amendments include:
 - 7.2.1.1. Additional study sites to be added;
 - 7.2.1.2. Small changes in the informed consent form;
 - 7.2.1.3. Changes in background information or update of literature review;
 - 7.2.1.4. Extension of the period of study;
 - 7.2.1.5. Changes that will not affect the study design and will not affect study outcomes or results;
 - 7.2.1.6. Administrative changes; and/or
 - 7.2.1.7. Stricter inclusion or exclusion criteria.
 - 7.2.2. **Major Amendments:** These amendments require a change to the study methodology or procedures that may result in an alteration of the risk benefit profile of the study. These amendments include:
 - 7.2.2.1. Change in study aims, objectives or design;
 - 7.2.2.2. Resulting changes to consent documents;
 - 7.2.2.3. Additional study procedures; and/or
 - 7.2.2.4. Easing of inclusion or exclusion criteria.
- 7.3. Approval for any protocol amendments should be submitted to the SACAP REC by completing the *SACAP REC Research Application for Amendment to Approved Study*

(Annexure A of SOP 12: Protocol Amendment Procedures). This form should then be submitted electronically to the REC Administrator via email.

- 7.4. The submission will then be placed on the agenda of the following SACAP REC session by the SACAP REC Administrator for consideration by the ethics committee. All SACAP REC ethics committee members review the submission as per the agenda circulated one week in advance of the meeting.
- 7.5. The lead member of the original application will be requested to present the amendments to the committee and highlight the differences between the original protocol and the amendments requested. If the original lead member is no longer on the committee, another committee member will be requested to lead the review and present the amendments. This will require access to the previous submission and a thorough consideration of all information that was presented for the original protocol.
- 7.6. The decision by the committee is minuted by the SACAP REC Administrator.
- 7.7. A new decision letter is issued clearly indicating the nature of the approval as related to Research Amendments, e.g. Ethics Approval for Research Amendment July 2021 and the date on which this was considered.

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 (SOP) and guidelines* (4.2).

ANNEXURE A:**SACAP REC APPLICATION FORM FOR AMENDMENT TO APPROVED STUDY**

Sometimes your research plans change and you need to alter your study in some way. The SACAP REC needs to be informed of any significant changes that may potentially impact on the risk category of your study. Any change on your ethics application documents is termed an *addendum*.

It is the responsibility of the researcher(es) and their respective supervisor to submit an application for any minor/major amendment to an approved study prior to the implementation of such an amendment. Retrospective application and approval of study amendments are not permitted under any circumstances.

The application will be subject to an expedited review where after approval/non-approval (with reasons, if applicable) of the application is issued to the researchers in writing. Upon receiving written approval for the amendment, the researchers may implement the amendment to the study (in particular data collection activities).

Unless there are extenuating circumstances, continuous applications for amendments to a particular study will not be viewed in a favourable light.

This application is not for requesting approval for an extension/renewal of a previously approved research proposal/protocol (for this please make use of the application form: Application to the SACAP REC for ethical approval of research involving human participants).

Where you need to make an addendum (i.e. where the SACAP REC needs to be informed)

- If you want to add/remove an instrument of data collection,
- If you want to change your method(s) of data collection,
- If you want to add/remove a certain participant group,
- If you want to add/remove any additional researchers,
- If you want to add a new site of investigation that may require an additional permission letter,
- If you are substantially changing the project title (not just a word here or there).
- If you are changing your aims or objectives,

Where you do NOT need to make an addendum (i.e. where the SACAP REC do not need to be informed)

- If you are changing your supervisor.

How to make an addendum

You need to send documents by email to the SACAP REC Office rec@sacap.edu.za.

The documents needed are as follows:

- A letter of motivation, stating clearly what you want to change and why,
- A copy of the original clearance certificate/clearance number,
- Any additional forms (information sheets, consent forms, drafts of the instruments to be used),
- Any additional permission letters, if appropriate,
- Complete the SACAP REC Application form for amendment to approved study to reflect the changes you want to make.

What happens next

The addendum documents will be sent to the two reviewers who considered your original application, and you will receive feedback by email if the documents provided need to be changed. If everything is in order, you will be informed by email that your changes are approved, and the documents will be added to your application. It remains the responsibility of the researcher (es) and supervisor(s) to conduct research in an ethical manner and ensure that any and all amendments to the project required by the SACAP REC are made before the research project commences.

SECTION 1: RESEARCH PROPOSAL/PROJECT SUMMARY	
DETAILS OF THE RESEARCH PROJECT	
Title of project	
Research design	(e.g. qualitative/quantitative/mixed-methods/action research)
Data collection method	(e.g. questionnaires/surveys/document analysis/structured interviews semi-structured interviews/ open-ended interviews)
Brief description of the research participants	(e.g. inclusion and exclusion criteria)
Level of risk	(low, medium, high)
Research setting	
SACAP REC Approval Code: *Refer to Ethics Approval Letter(s)	
Current Ethics Approval Granted until: *Refer to Ethics Approval Letter(s)	
DETAILS OF THE RESEARCHERS, SUPERVISOR AND COLLABORATORS	
Researcher name(s)	
Researcher email address(s)	
Programme	

Research supervisor	
Supervisor email address	
If your research is being conducted within an company, organisation or intuition, please provide the details of the contact person	
Name	
Contact number	
Email Address	
Role in Organisation	

SECTION 2: STATUS OF DATA COLLECTION PROCEDURE(S)			
Has recruitment commenced?		Yes	No
If NO, please provide reasons below for not having yet commenced with recruitment of participants or state non-applicable.			
Date recruitment commenced and is currently continuing			
Date recruitment commenced on		Date recruitment closed on	
Date data collection-related activities commenced on		Date data collection-related activities closed on	
Data collection related activities are complete, follow-up activities only		Yes	No
SECTION 3: PREVIOUS AMENDMENTS/EXTENSIONS/RENEWALS			
No amendments/extensions/renewals have been made since original approval of study		Yes	No
All amendments/extensions/renewals to the original study have already been requested and approved by the SACAP REC (provide a brief summary of all previous amendments/extensions/renewals previously approved below or state non-applicable)			
SECTION 4: PROPOSED CHANGES WILL AFFECT (indicate with an 'x' all that are applicable)			
Study aims/objectives and/or design			
Study data collection instruments (e.g. interview schedules, questionnaires)			
Recruitment method(s) and/or materials (e.g. advertisements)			

Eligibility requirements (i.e. increasing inclusion criteria and/or decreasing exclusion criteria) for fair selection of participants	
Enrolment method(s)	
Data collection and/or data analysis method(s)	
Consent form and/or written/oral information	
Risk to participants (i.e. there will be new/increased risk/discomfort/inconvenience to participants)	
Risk to researcher(s) (i.e. there will be new/increased risk to researchers)	
Other, please specify Provide description of major amendment(s)	

SECTION 5. FOLLOW-UP ACTION(S) FOR ALREADY ENROLLED PARTICIPANTS (indicate with an 'x' all that are applicable)			
Inform currently enrolled participants as soon as amendment is approved			
Re-consent currently enrolled participants with revised consent/assent forms and/or oral/written information			
No action required			
Eligibility requirements (i.e. increasing inclusion criteria and/or decreasing exclusion criteria) for fair selection of participants			
Other, please specify Provide description of follow-up action(s) below:			
SECTION 6: LIST OF PROPOSED AMENDMENTS			
Please itemise below each individual amendment that requires review and approval (add additional pages as an Appendix to this application if required). A copy of the itemised list will be returned to the PI and PRP as notification of the extent of amendment approval.			
Amendment Reference	FOR OFFICIAL USE ONLY Approval Status		FOR OFFICIAL USE ONLY Comments
	Approved	Not Approved	
1. Brief descriptor of amendment attached as Appendix A.			
2. Brief descriptor of amendment attached as Appendix B.			
3. Brief descriptor of amendment attached as Appendix C.			
4. Brief descriptor of amendment attached as Appendix D.			

5. Brief descriptor of amendment attached as Appendix E.			
SECTION 7: DETAILED DESCRIPTION OF PROPOSED AMENDMENTS			
<p>For each of the listed amendments above, attach as clearly labelled appendices to this application:</p> <ol style="list-style-type: none"> 1. A detailed description/explanation of the amendment; 2. Detailed rationale/justification for the amendment; and 3. Copies of any and all relevant revised documentation (if applicable) for the amendment, in particular: <ol style="list-style-type: none"> a. One copy of each amended document clearly highlighting the changes from the currently approved document (highlighting of changes can be implemented by means of tracked changes, striking through “old text” and showing the “new text” in bold, underlined or italics, or similar); and b. One clean copy of each amended document. 			
SECTION 8: ADDITIONAL COMMENTS			
<p>I would like the SACAP REC to take note of the following additional information. (Please provide a brief summary below or state Non-Applicable)</p>			

Personal Declaration of Responsibility:

- I/We subscribe to the following ethical principles:
 - *Voluntary participation* in research, in that participants are not coerced, can decline to participate and may withdraw from the research at any time.
 - *Informed consent* which means that research participants must at all times be fully informed about the research process and purposes, and must give consent to participate in the research.
 - *Safety in participation* meaning the participants should not be placed at undue risk or harm of any kind.
 - *Privacy* implying that the confidentiality and anonymity of participants must be protected at all times.
 - *Trust* meaning that human participants will not be exposed to any acts of deception in the research process or its published outcomes.
- I/we disclosed all relevant information which may reasonably have an impact on the decisions made by the SACAP Research Ethics Committee.
- I/we declare that we have not yet engaged with data collection in this study.
- I/we are responsible for ensuring that all documents relevant to this study, such as letters of permission and informed consent must be retained for safekeeping.
- I/we declare that all relevant role-players have signed this application.
- I/we declare that we have included a participant information sheet and consent form that will provide the conditions of participation and informed consent.

- I/we declare that we have included copies of the data collection protocols, such as questionnaires and/or interview schedules as well as all other relevant research documentation where applicable.
- I/we declare that all information provided in this application is truthful and that my/our research supervisor is aware of the contents herein.
- I/we understand that any further amendment to the approved protocol needs to be submitted to the SACAP Research Ethics Committee for review before data collection. Non-compliance means data collection cannot proceed.

_____	_____
Research applicant's signature	Date
_____	_____
Research applicant's signature	Date
_____	_____
Research applicant's signature	Date
_____	_____
Research applicant's signature	Date
_____	_____
Research applicant's signature	Date
_____	_____
Supervisor's signature	Date

SECTION 9: DECLARATION BY THE RESEARCHER AND SUPERVISOR			
<p>I/We, the signatories, declare that all information on this form is correct, including attached progress reports are complete and accurate, and that we will strive to maintain the highest ethical standards in this research at all times, according to norms and expectation of the Faculty of Applied Psychology/Social Work and Community Development/Management and Leadership and SACAP REC expectations, recognising that ethical practice in research is always a continuing process.</p>			
Researcher Full Name			
Researcher Signature		Date	

Researcher Full Name			
Researcher Signature		Date	
Researcher Full Name			
Researcher Signature		Date	
Researcher Full Name			
Researcher Signature		Date	
Supervisor Full Name			
Supervisor Signature		Date	

FOR OFFICIAL USE ONLY			
This serves as notification of minor/major amendment approval (Please indicate with an 'x' in the corresponding box)			
Approved			
Partially approved (refer to copy of Section 6 returned to PI and PRP)			
Not approved (Refer to comments section below)			
SACAP REC Chair Signature		Date	
SACAP REC Chair Full Name			
Comments to Researcher and Supervisor from the SACAP REC			