

## SOP 18: Scientific Review Committee

The South African College of Applied Psychology Review Ethics Committee (SACAP REC)	
<b>Title</b>	SOP 18: Scientific Review Committee
<b>SOP No.</b>	SOP 18_ SACAP REC _18.1
<b>Date of approval</b>	
<b>Revision date</b>	
<b>Pages</b>	28

### 1. COMPILATION AND AUTHORIZATION

Action	Designated person	Date	Signature
<b>Compiled for SACAP by:</b>	REC Office	February 2022	
<b>Amended for SACAP by:</b>			
<b>Checked by:</b>	Academic Manager		
<b>Authorised by:</b>	Academic Dean		

### 2. DOCUMENT HISTORY

Date	Version no	Reason for revision
February 2022	1	Development of the document

### 3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
<b>SOP</b>	Standard Operating Procedure/s
<b>SACAP REC</b>	The South African College of Applied Psychology Research Ethics Committee

SRC	Scientific Review Committee
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#### 4. PURPOSE OF THE SOP

The purpose of this SOP is to provide background and a framework for the scientific review of applications prior to serving at the SACAP REC.

#### 5. SCOPE

The scope of this document covers the procedure(s) to be followed, possible outcomes and appeals procedures for SACAP SRC applications.

#### 1. AUTHORITY OF THE SACAP SRC

The SACAP SRC derives its authority as a subcommittee of the SACAP REC, which in turn derives its authority from the National Health Act No. 61 of 2003 which provides statutory authority for the governance of "health research" through the registered RECs, as well as the necessary ethics regulatory infrastructure through the NHREC.

The SACAP SRC further derives its authority from the Department of Health's (2015) *Ethics in Health Research: Principles, Processes and Structures* which describe the minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research. As such the SACAP SRC is charged with the scientific and methodological review of proposals prior to REC review, pursuant to National Health Act No. 61 of 2003 and the Department of Health's minimum national benchmark of norms and standards

#### 2. ROLES AND RESPONSIBILITIES

The roles and responsibilities of the SACAP SRC are stipulated below and developed from national and international standards for scientific review.

- 2.1. The primary responsibility of the SACAP SRC is to conduct rigorous scientific reviews of all research proposals involving humans to assess the study's scientific quality and operational feasibility, ensuring that protocol can be completed. The review also aims to ensure the protocol will achieve its objectives so that the fewest number of participants are exposed to risk to answer the study question and that the study question is significant and relevant.
- 2.2. Furthermore, the SRC aims to promote the highest scientific standards and best available techniques or approaches for optimal use of participating humans.
- 2.3. The primary responsibility of each SACAP SRC member is to decide independently whether the proposed research meets the accepted scientific norms and standards. In doing so, SRC members will review:
  - 2.3.1. Scholarship and pertinence of background material and rationale
  - 2.3.2. The clarity and appropriateness and relevance of the research question;
  - 2.3.3. The appropriateness and efficiency of the research design;
  - 2.3.4. The rigor, feasibility and methodological coherence of the chosen methods;
  - 2.3.5. The qualifications and expertise of the research team;

- 2.3.6. The adequacy of sample size and relevance of controls; and
- 2.3.7. The validity of the statistical analysis plan.
- 2.4. The scientific review will always prioritise participant interests and welfare over the interest of the scientific project. The SACAP SRC will further:
  - 2.4.1. Function according to a strict professional code of conduct as appropriate, including SACAP's institutional Code of Conduct.
  - 2.4.2. Ensure confidentiality of all information revealed to it.
  - 2.4.3. Ensure that all researchers sign the SACAP REC's Research Ethics Code of Conduct.
  - 2.4.4. Ensure that researchers have a proper understanding of methodological soundness, as applicable to the specific research conducted within the relevant disciplines.
  - 2.4.5. Receive applications for scientific approval from researchers via the REC Office.
  - 2.4.6. Discuss, decide, and communicate the SACAP SRC's decisions regarding applications to applicants through the REC Office, administered by the REC Administrator.
  - 2.4.7. Approve research by the issuing of scientific review certificates indicating their eligibility to serve at the SACAP REC for ethical review.

### **3. MEMBERSHIP**

#### **3.1. SRC Chair**

As a sub-committee of the SACAP REC, the SRC Chair is appointed by the REC Office. As soon as the SACAP REC becomes aware of a vacancy in this position, the Academic Head of the institution (Academic Dean) is notified by the REC Administrator. The Academic Dean of the institution will liaise with the REC Administrator to notify all staff members through emails about the vacant position of SACAP REC Chair. The call for application of such a position should clearly indicate that the possible candidate must have experience as a REC member and a proof of knowledge in research methodology and ethics obtained within the past three years. CVs are sent to the SACAP REC Administrator. The Head of the institution or a delegated person, the SACAP REC Administrator and at least two REC members will do the shortlisting. The Academic Dean or delegated person and the existing Chair will have preliminary discussions with the suggested candidates on the roles and responsibilities of this position. A final decision is given at a special sitting. A formal letter of appointment is sent by the SACAP REC Administrator setting out the term of office; where to find the necessary information pertaining to the SACAP REC and SRC and the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the REC. In the event wherein the current SRC Chair resigns or in case of death, an acting Vice Chair can be appointed by the REC to act for a limited period as temporary measure while the process of appointing the permanent Chair unfolds. The Vice Chair will carry out the duties of the Chair in their absence and will have oversight of all SRC processes and operations. The Vice Chair is also responsible for ensuring and promoting the highest attainable quality of scientific and ethical research within the institution in line with the SACAP policy on Research Ethics.

#### **3.2. Composition and selection of the SACAP SRC:**

The composition of the SRC is determined by the SRC Chair in accordance with the discipline specific requirements of the proposals that the SRC undertakes to review. As such the SRC should be independent, multi-disciplinary, multi-sectoral and pluralistic.

##### **1.1. Selection and Appointment of SACAP SRC members**

- 1.1.1. Members whose REC membership is not a condition of employment are appointed

for a term of one years and may be re-appointed for further terms should they be agreeable;

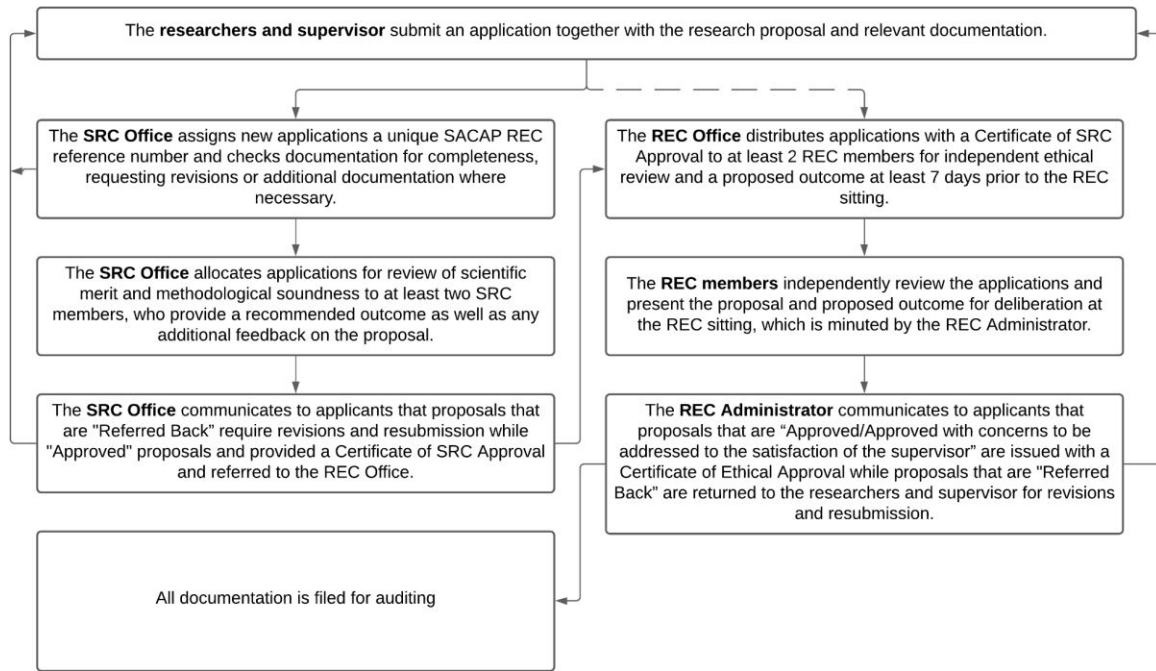
- 1.1.2. Updated CVs of all SRC members should always be on file by the SRC Office; and
- 1.2. **The Selection and Appointment of SRC:** Academic staff members whose SRC membership is a condition of employment are appointed as SRC members by virtue of their agreed job description and serve the SRC until otherwise agreed or their resignation. Updated CVs of all SACAP SRC members shall always be kept on file by the SRC Office. Other SRC members are appointed on an ad hoc basis by the SRC Chair.
- 1.3. **Resignations:** Committee members may resign from the SACAP SRC committee after giving one month's notice. The notice must be in writing and sent to the SACAP SRC Chair.
- 1.4. **Training:** Training of all SACAP SRC members in the principles of research methodology is critical, to fulfil their duties as SACAP SRC members to the highest standard possible. As such all SRC members receive appropriate training provided as part of the induction process of all new SRC members. Further opportunities for training may be provided at the discretion of the SRC Chair. All training attended by SRC members will be documented and stored for recordkeeping purposes.
- 1.5. **Code of Conduct:** SACAP SRC members are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. All SACAP SRC members will be expected to sign code of conduct. Over and above this code of conduct, it will be expected of SACAP REC members to:
  - 1.5.1. Agree to a term of office of one (1) years;
  - 1.5.2. Familiarise themselves with the institutional policies and procedures as well as national and international research ethics guidelines;
  - 1.5.3. Attend the induction training sessions to keep abreast with the latest changes in this field;
  - 1.5.4. Always act with integrity;
  - 1.5.5. Be punctual in the submission of SRC documentation; and
  - 1.5.6. Diligently perform all responsibilities delegated to them.

If members act in good faith, they are indemnified from personal liability as stipulated in the SACAP REC TOR.

## 6. PROCEDURE

Local and international norms and guidelines, as well as the SACAP REC's SOP 4: Proposal Applications and Decisions mandates that all proposals that are submitted to the SACAP REC must be accompanied by a scientific report or letter signed by the SRC Chair.

Figure 1 demonstrates the ethics approval process, including prior review by the SRC.



The review procedure for the SRC will operate as follows:

- 6.1. The researchers submit SACAP's Application Form together with the research proposal to the REC Office.
- 6.2. The SRC Office assigns the application a unique SACAP REC reference number and assesses the documents for completeness, requesting additional information, and revisions from applicants and supervisors where necessary.
- 6.3. The SRC Office allocates the application research proposal for review to at least two SRC members.
- 6.4. The SRC members independently review the scientific merit and methodological soundness of the proposal and provides a recommended outcome as well as any additional feedback on the proposal.
- 6.5. The SRC Chair communicates the outcome and feedback with the REC Administrator and the applicants.
  - 6.5.1. Applications that are "Referred Back" by the SRC require additional revisions, in accordance with the feedback provided, to the research protocol in order to be Approved.
  - 6.5.2. Applications that are "Approved" are given a Certificate of SRC Approval and referred to the REC Administrator for REC review.
- 6.6. Applications with a Certificate of SRC Approval are distributed to at least two REC members for review, at least seven days prior to the sitting.
- 6.7. The reviewers independently review the proposal and document a recommended outcome, together with their reasoning and general recommendations.
- 6.8. The reviewers present the proposal to the committee at the scheduled sitting for deliberation and to have an outcome assigned.
- 6.9. The outcome is minuted by the REC Administrator and communicated with applicants within ten working days of the decision.

- 6.9.1. Applicants of proposals that are “Approved” are notified and issued with a Certificate of Ethical Approval which is valid for two years.
  - 6.9.2. Applicants of proposals that are “Approved with concerns to be addressed to the satisfaction of the supervisor” are issued with a Certificate of Ethical Approval together with a list of concerns that must be addressed to the satisfaction of the supervisor, prior to the commencement of data collection.
  - 6.9.3. Applicants of proposals that are “Referred Back” are notified and are invited to resubmit their application pending revisions in accordance with the outcome and feedback provided.
- 6.10. All documentation is filed for auditing. The SACAP REC Chair of this committee has authority to deal with minor matters related to the applications for scientific and ethical clearance submitted. The Chair will consult other members when appropriate. Outcomes should be reported to and be made available to all members at the next sitting of the committee.

## **7. UNFAVOURABLE DECISIONS**

- 7.1. The SRC can ask for revisions and/or amendments before scientific approval can be re-considered.
- 7.2. If an adverse decision is made the supervisor/researcher is contacted within ten days of the decision, via e-mail together with a letter of the conditions that need to be met.
- 7.3. Proof of actions taken by the researchers to address the conditions as specified in SACAP SRC outcome letter has to be submitted to the SACAP SRC for review.
- 7.4. Proof of these actions must be submitted as a complete set of documents addressing all the required conditions.
- 7.5. Resubmissions that have addressed the concerns raised by the SRC will be sent to one the original reviewers for their opinion. Depending on the comments of the reviewer(s) an approval letter will be issued or otherwise the comments will be forwarded in writing to the researcher.
- 7.6. If additional/outstanding responses to conditions are required or the reviewers are not satisfied with the actions taken by the researcher, the researcher will be informed in writing of the outcome of the review of the actions.
- 7.7. Amendments to already referred back proposals can, if urgent, be approved by the Chair of the SACAP SRC.

## **8. EXPEDITED APPROVAL**

The SACAP SRC reviews research applications in exceptional circumstances. The SACAP SRC can only ratify expedited decisions from another registered HREC or in low or negligible risk cases. The Chair and one additional SRC member will review the application. Expedited reviews or approvals are only done in:

- Clearly justified and motivated cases;
- In cases of urgency;
- A time factor;
- Administrative changes;
- Additional researchers/personnel that need to be included in the study;

- Amended certificates;
- Amendments that would not harm the patient/participant; and
- Amendments to the research protocol that should not alter the original research methodology. This would include any documentation necessary to explain the processes.

If the SRC Chair grants expedited approval, the researcher is informed thereof within seven working days after submission and research may continue as stipulated as soon as the expedited approval letter has been received. It is noted in the application that the protocol review was expedited.

- 1.6. **Conflict-of-interest:** All SACAP REC members will be required to sign a conflict-of-interest (COI) agreement at the annual onset of their term of office (*Annexure D of SOP 2: The Selection, Appointment and Functioning of REC Members*). In this agreement, laid out in Section 6 of the letter of appointment, SACAP REC members must disclose to the SACAP REC Chair any actual, potential and perceived potential COI relating to the application for ethical approval of research in the course of duties performed in the service of the SACAP REC by completing the COI declaration form and submitting this to the SACAP REC Chair (*Annexure F of SOP 2: The Selection, Appointment and Functioning of REC Members*). No member may participate in the review of any proposal/project in which a member has a conflict of interest, except when requested to provide information by the SACAP REC Chair. Members who have conflicts of interest are required to disclose such conflicts and excuse themselves from deliberations on the relevant research proposals/projects. In such cases, the SACAP REC Chair of the SACAP REC, shall have the power to co-opt additional members. (*See section 7.9 and Annexure E of SOP 2: The Selection, Appointment and Functioning of REC Members*).
- 1.7. **Confidentiality:** All SACAP REC members will be required to sign a confidentiality agreement at the onset of their term of office. In this agreement, laid out in Section 5 of the letter of appointment, SACAP REC members declare that they will keep confidential all the documents, discussions and deliberations of REC duties. (*Annexure F SOP 2: The Selection, Appointment and Functioning of REC Members and Section 11.4 of SACAP REC TOR*).

## 9. REFERENCE DOCUMENTS

- Department of Health. (2015). *Ethics in health research: Principles, processes and structures*.
- UNISA. (2015). *Terms of reference: UNISA Research and innovation ethics review committee (URIERC)*.
- Scientific Review Committee: <https://ovpr.uchc.edu/services/rics/hspp/scientific-review-committee/>
- Selker, H. P., Welch, L. C., Patchen-Fowler, E., Breeze, J. L., Terrin, N., Parajulee, A., LeClair, A., Naeim, A., Marnocha, R., Morelli Novak, J., Caldwell, C. S., Cola, P. A., Croker, J. A., Cifu, D. X., Williams, K. M., Snyder, D. C., & Kitterman, D. (2020). Scientific Review Committees as part of institutional review of human participant research: Initial implementation at institutions with Clinical and Translational Science Awards. *Journal of clinical and translational science*, 4(2), 115–124.