

## Terms of Reference for SACAP's Research Ethics Committee

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
<b>Title</b>	Terms of Reference for SACAP's Research Ethics Committee
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### 1. COMPILATION AND AUTHORISATION

Action	Designated Person	Date	Signature
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<b>Revised by</b>	Dr Diana De Sousa: SACAP REC Chair	14 August 2023	D. De Sousa

### 2. DOCUMENT HISTORY

Date	Version no.	Reason for revision
March 2019	1	Development of the document
July 2021	2	Recommendations by NHREC
August 2023	3	Clarify authority and reporting lines.

### 3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
<b>NHREC</b>	National Health Research Ethics Council
<b>SACAP</b>	South African College of Applied Psychology
<b>SRC</b>	Scientific Review Committee

<b>CIOMS</b>	Council for International Organizations of Medical Sciences
<b>HPCSA</b>	Health Professions Council of South Africa
<b>SA</b>	South Africa
<b>CV</b>	Curriculum Vitae
<b>TIE</b>	Time, Inconvenience and Expenses
<b>REC</b>	Research Ethics Committee
<b>COI</b>	Conflict of interest
<b>DOH</b>	Department of Health

#### 4. INTRODUCTION

In line with SACAP's *Research and Ethics Policy* international and national research ethics codes and guidelines require that all research conducted on human participants be reviewed and approved by an independent research ethics committee (REC) before the research study is carried out.

#### 5. PURPOSE OF THE TOR

The main purpose of the SACAP REC is to promote the conduct of ethical research within the College. The duties, responsibilities and reporting tasks of the SACAP REC are guided by the Department of Health (2015) *Ethics in Health Research: Principles, Processes and Structures*.

The essential function of the REC is to independently review the proposals of research projects proposed by students and staff members of SACAP and to monitor the implementation of the proposed research. The REC is also available to review, advise on, and approve or reject research proposals involving human participants submitted to it by researchers who are not members of SACAP. The REC does not review monitoring and evaluation of institutional processes related to academic standards and quality assurance enhancement and as such treats these quality assurance processes as artefacts. Additionally, while the REC avails itself to advise in all research related matters, it does not evaluate informal research associated with the teaching of research methodology at an undergraduate level.

The SACAP REC is guided by ethical awareness, the protection of human rights, and social justice, and endeavours to clarify all matters pertaining to ethical aspects of research. Special attention will be paid to research that includes vulnerable participants/populations (*See SOP 5: Research Involving Minors, Working with Vulnerable Groups and Populations*), as well as honouring the principle of informed consent (*See SOP 13: Informed Consent*), privacy and that all obtained information must be handled in a confidential manner and with sensitivity (*See SOP 10: Research Participants' Right to Privacy and Confidentiality & SOP 11: Data Management, Collection and Storage*), and with the option to enquire further about their rights as research participants as well as to raise concerns directly with the SACAP REC (*See SOP 16: Whistleblowing Pertaining to Research*).

#### 6. SCOPE

The SACAP REC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of research proposals that are submitted to it.

Ethical approval must be obtained for all research proposals before a research study commences. The SACAP REC will register under the National Health Research Ethics Council (NHREC) and will always function according to the requirements as stipulated by the following legislative frameworks and codes:

- I. National Health Act No. 61 of 2003;
- II. The associated regulations (regulations Relating to Research with Human Participants, 19 September 2014);
- III. The guidelines of the Department of Health (Department of Health 2015 Ethics in Health Research: Principles, Processes and Structures, 2015);
- IV. Children's Act No. 38 of 2005 as amended;
- V. Older Persons' Act No. 13 of 2006;
- VI. The South African Constitution (Act 108 of 1996);
- VII. National and international research ethics guidelines;
- VIII. Protection of Personal Information Act (Act 4 of 2013) - Section 29(a);
- IX. Health Professions Council of South Africa (HPCSA);
- X. Guidelines for good practice in the health care professions;
- XI. General ethical guidelines for health researchers, booklet 6, Pretoria, May 2008;
- XII. Guidelines for good practice in the conduct of clinical trials with human participants in South Africa;
- XIII. Declaration of Helsinki, World Medical Association;
- XIV. International ethics guidelines for biomedical research involving human subjects;
- XV. Council for International Organizations of Medical Sciences (CIOMS); and
- XVI. Human Sciences Research Council (South Africa): Research Code

SACAP REC will not consider research studies for approval if it is apparent that the research has already been conducted, i.e., retrospective ethical approval will not be given.

## 7. AUTHORITY OF THE SACAP REC

The National Health Act No. 61 of 2003 provides statutory authority for the governance of health research through the registered RECs (Research Ethics Committees), as well as the necessary ethics regulatory infrastructure through the NHREC. The SACAP REC further derives its authority from:

- The governance rules formulated by the SACAP REC;
- The minimum standards and guidelines for research ethics of the NHREC;
- The *National Health Act No. 61 of 2003, section 73*, which requires the institutions to establish RECs which are registered with the NHREC;
- The Department of Health's minimum national benchmark of norms and standards for conducting responsible and ethical health and health-related research *Ethics in Health Research: Principles, Processes and Structures, 2015* (chapter three and four); and
- The Rules for the Management of Research Ethics at SACAP.

In all instances the latest versions or amendments of the Act, regulations or standards will take

immediate effect as they are published or promulgated, where this TOR will then be amended as soon as possible to reflect the latest changes.

In terms of authority lines and reporting lines, the SACAP REC operates within a clear authority framework that ensures transparency, accountability, and effective decision-making. The SACAP REC reports directly to the executive management of the institution. This reporting relationship facilitates timely communication, alignment of ethical considerations with organizational goals, and the integration of ethical guidelines into research initiatives.

SACAP Executive management plays a pivotal role in supporting the SACAP REC's research endeavours. They provide strategic guidance, allocate necessary resources, and endorse the SACAP REC's decisions to ensure that ethical considerations align with the institution's vision and mission. SACAP Executive management collaborates with the SACAP REC to create an environment that promotes ethical research practices and safeguards the rights and well-being of research participants. The SACAP REC operates as an independent body while working in close collaboration with SACAP executive management. Ethical considerations, recommendations, and decisions made by the SACAP REC are communicated to the executive management for endorsement and support. This collaborative approach ensures a balanced integration of ethical principles with the organization's overall research objectives.

Regular reporting mechanisms are established to maintain transparency and accountability between the SACAP REC and SACAP executive management. The SACAP REC submits periodic reports to executive management outlining its activities, key ethical decisions, and recommendations. This reporting mechanism fosters open dialogue and mutual understanding of ethical considerations and their impact on research initiatives.

The SACAP REC and SACAP executive management work in tandem to align ethical oversight with the institution's goals. Ethical considerations form an integral part of research planning, execution, and dissemination. The SACAP REC's recommendations and decisions are instrumental in ensuring that research initiatives not only adhere to ethical standards but also contribute positively to the organization's mission and reputation.

These authority lines and the role of SACAP executive management in the SACAP ToR underscores the SACAP REC's commitment to ethical research practices while harmonizing these practices with the strategic direction of the organization. This collaborative approach ensures ethical integrity and upholds the organization's ethical responsibilities in the realm of research.

## **8. ROLES AND RESPONSIBILITIES**

The roles and responsibilities of the SACAP REC are stipulated below and are adapted from the Department of Health (2015) *Ethics in Health Research: Principles, Processes and Structures guidelines*.

- 8.1. The main responsibility of SACAP REC is to conduct rigorous ethics reviews of all research proposals involving humans to ensure that the welfare and other interests of participants and researchers are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.
- 8.2. SACAP REC must ensure that research proposals submitted for ethical scrutiny have been reviewed by the Scientific Review Committee (SRC). The confirmation letter from the SRC Chair is done through the office of the SACAP REC Administrator.
- 8.3. SACAP REC must ensure that the submitted research proposals are appropriate to the discipline concerned.
- 8.4. The reviewers must maintain ethical and scientific standards to:

- 8.4.1. Protect participants from harm by weighing the risk of harm against the likelihood of benefit;
  - 8.4.2. Hold researchers accountable for their research activities;
  - 8.4.3. Promote the highest scientific standards and best available techniques or approaches for optimal use of participating humans; and
  - 8.4.4. Promote important social and ethical values.
- 8.5. The SACAP REC must review research proposals prospectively (not retrospectively) to ensure that they meet the accepted ethical norms and standards before research commences, using the guidelines indicated in the Department of Health (2015) *Ethics in Health Research: Principles, Processes and Structures* document as a minimum benchmark.
- 8.5.1. The primary responsibility of each SACAP REC member is to decide independently whether the proposed research study protects the interests of participants adequately and upholds exemplary standards.
  - 8.5.2. In the case of research with vulnerable groups (children, older persons, women, people with disabilities, and prisoners) relevant national and international legislative frameworks should be considered as guidelines.
  - 8.5.3. To apply and maintain the highest ethical principles that govern the conduct of research on human participants.
- 8.6. Such responsibility regarding participant interests and welfare shall always take precedence over the interest of the scientific project. The SACAP REC will further:
- 8.6.1. Function according to a strict professional code of conduct as appropriate, including SACAP's institutional Code of Conduct.
  - 8.6.2. Ensure confidentiality of all information revealed to it.
  - 8.6.3. Ensure that all researchers sign the SACAP REC's Research Ethics Code of Conduct.
  - 8.6.4. Ensure that researchers have a proper understanding of research ethics, as applicable to the specific research conducted within the relevant disciplines.
  - 8.6.5. Receive applications for research ethics approval from researchers via the REC Office, administered by the REC Administrator.
  - 8.6.6. Discuss, decide, and communicate the SACAP REC's decisions regarding applications to applicants will be sent out by the REC Office, administered by the REC Administrator.
  - 8.6.7. Approve research by the issuing of research ethics approval certificates (valid for two years) for approved projects.
  - 8.6.8. Consider and approve any amendments to the original approved research proposal.
  - 8.6.9. Implement and manage a monitoring system for approved projects that includes a reminder system in accordance with the approved research's risk level, the evaluation of the submitted reports, as well as providing written approval for continuation of the study.
  - 8.6.10. Consider and act appropriately in cases of ethical misconduct by researchers.
  - 8.6.11. Report all ethical matters to the REC Chair via the REC Office, administered by the REC Administrator.
  - 8.6.12. Report to the NHREC on an annual basis, using the NHREC template.

## 9. MEMBERSHIP

### 9.1. Composition of the SACAP REC:

The composition of the REC is determined by legal requirements, as set out by the NHREC guidelines. The REC should be independent, multi-disciplinary, multi-sectoral and pluralistic. Furthermore, membership of the SACAP REC will as far as possible reflect the diversity of the South African society.

The membership of the REC is composed of the following individuals:

- 9.1.1. The REC Chair;
- 9.1.2. At least nine members, with a quorum being a simple majority;
- 9.1.3. Where the number of members is more than 15, the quorum may be 33%;
- 9.1.4. At least one lay person;
- 9.1.5. At least one member with knowledge of and current experience in the professional care, counselling, or health-related treatment of people;
- 9.1.6. At least one member with professional training and experience in qualitative research methodologies;
- 9.1.7. At least one member with professional training and experience in quantitative methodologies;
- 9.1.8. At least one member with expertise in biostatistics;
- 9.1.9. At least one member with expertise in research ethics;
- 9.1.10. At least one member who is legally qualified; and
- 9.1.11. A REC Administrator.

### SACAP REC Membership Statistics

Item	Number	Disciplines
<b>Total Members</b>	47	Apart from other disciplines in the REC, members are from various disciplines of Psychology and Social Work professionals are from various fields of specialties which led to the recruitment into the REC. These members are drawn from the faculties that produce research that the SACAP REC primarily reviews: <ul style="list-style-type: none"> <li>● Research Psychology</li> <li>● Counselling Psychology</li> <li>● Educational Psychology</li> <li>● Industrial Psychology</li> <li>● Social Work</li> </ul>
<b>Gender</b>		
Male	8	
Female	39	
<b>Race</b>		
Black African	11	
White	24	
Indian	2	
Coloured	7	
Other	3	
<b>Profession</b>		
Psychology	40	
Social Work	4	
Management & Leadership	2	
Education	1	
<b>Designation</b>		
SACAP REC Chair	1	
Members with professional training and experience in qualitative research methodologies	12	
Members with professional training and experience in quantitative research methodologies	12	
Member with knowledge of and current experience in the professional care, counselling or health-related treatment of people	7	
Members with expertise in biostatistics	2	
Members with expertise in research ethics	16	
Members who are legally qualified	2	
Layperson	1	
Administration Officer	1	
<b>Ethics Training</b>		
Trained	47	
Not trained	0	

- 9.2. **Selection and Appointment:** For REC members whose REC membership is not a condition of their employment at SACAP, REC members are appointed for a term of three years and may be re-appointed for another single term. A break of at least two years is needed before a member can be re-appointed after two terms. Updated CVs (Curriculum Vitae) of all SACAP REC members shall always be on file in the REC Office. Consideration must be given to succession planning. *(See SOP 2 for Selection, Appointment and Functions for SACAP REC)*
- 9.3. **Selection and Appointment of the SACAP REC Chair:** 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 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 ethics obtained within the past three years. CVs are sent to the REC Administrator. The Academic Dean or a delegated person, the 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 for pertaining to the SACAP REC and the assurance that the members are indemnified from personal liability against claims that may arise during the ordinary business of the REC. This appointment must reflect in the annual task agreement of the REC Chair. The NHREC is also notified. The length of term for the SACAP REC Chair is three years after which the Chair will step down and the procedure of the selection and appointment of a new Chair will be undertaken. In the event wherein the current Chair resigns or in case of death, an acting 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 Chair is responsible for presiding over SACAP REC sittings and to oversee all processes in the SACAP REC. The 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's Policy on Research Ethics through the following:
- 9.3.1. Ensuring that the records and documentation of the SACAP REC are secured and kept confidential;
  - 9.3.2. Representing the institution at NHREC annual and special sittings, and
  - 9.3.3. Submitting an annual report to the NHREC using the required template.
- 9.4. **Selection and appointment of the SACAP REC Vice Chair:** 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 will liaise with the REC Administrator to notify all staff members through emails about the vacant position of SACAP REC Vice 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 ethics obtained within the past three years. CVs are sent to the SACAP REC Administrator. The Academic Dean 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 the assurance that the members are indemnified from personal liability against claims that may arise during the ordinary business

of the REC. This appointment must reflect in the annual task agreement of the REC Chair. The NHREC is also notified. In the event wherein the current Vice 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. They will therefore be responsible for presiding over SACAP REC sittings and to oversee all processes in the SACAP REC. 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 Research Ethics Policy* through the following:

- 9.4.1. Ensuring that the records and documentation of the SACAP REC are secured and kept confidential;
  - 9.4.2. Representing the institution at NHREC annual and special sittings; and
  - 9.4.3. Submitting an annual report to the NHREC using the required templates
- 9.5. **Selection and Appointment of SACAP REC Committee Members:** Academic staff of SACAP, whose REC membership is a condition of employment by virtue of their position within the College, will be appointed as members of the SACAP REC. For the recruitment of persons outside of SACAP, as soon as the SACAP REC become aware of a vacancy, the SACAP REC Administrator will issue a call for interested persons with the relevant skills or from a specific profession to replace the specific gap the resignation has created, e.g. someone from a specific research entity and/or with specific skills as per requirement of the NHREC. The interested person will send the CV to the REC Administrator who will present it to the SACAP REC for deliberation and finalization. The current Chair has preliminary discussions with the nominated candidates on the roles and responsibilities of this position. SACAP REC is informed during a sitting and the appointment is finalized. A formal letter of appointment is sent by the REC Administrator, setting out the term of office; where to find the necessary information for new members; and the assurance that the members are indemnified from personal liability against claims that may arise during ordinary business of the REC. This appointment must reflect in the annual task agreement of the REC member. The NHREC is notified.
- 9.6. **Sub-Committees:** SACAP REC can establish various sub-committees, from within the membership of the SACAP REC, as per the needs and requirements, e.g., Executive Committee, incident, and Serious Adverse Events Committee, etc.
- 9.7. **Co-opted Members, Observers and Visitors:** The SACAP REC can co-opt members as and when needed. Observers and visitors will be allowed in exceptional cases or for specific purposes. Researchers can be invited for the discussion of their applications to clarify uncertainties.
- 9.8. **Training:** Training of all SACAP REC members in the principles of ethical research is critical, to fulfil their duties as SACAP REC members to the highest standard possible. In addition to training provided as part of the induction process of all new REC members, annual training on various topics pertinent to ethical research with human participants will also be made available to all REC members. All training attended by REC members both provided by the SACAP REC or external training attended by REC members within a two-year period is documented in a training register kept by the REC Administrator (*Annexure B of SOP 2: The Selection, Appointment and Functioning of REC Members*).

## 10. SACAP REC ADMINISTRATOR

The Academic Head of the institution (Academic Dean) or delegated person appoints the SACAP REC Administrator on a permanent basis whose responsibilities are to:

- Organize and maintain a register of the applications received and reviewed by the SACAP REC;
- Administer SACAP REC research ethics applications;
- Ensure that the register of the SACAP REC members is up to date;
- Provide the SACAP REC with secretarial services (taking attendance register, noting apologies for meetings, and writing minutes);
- Arrange all logistical aspects of SACAP REC meetings (inviting committee members to meetings (online or offline), training, venue booking (online or offline), and other necessities);
- Ensure that applications received are complete and comply with all the regulations, and that they are timeously referred to the SACAP REC members for review;
- Ensure the smooth running of administrative and logistical functions;
- Organize and maintain a register of research proposals reviewed by the SACAP REC;
- Distribute ethics approval certificates or ethics review report, or rejection thereof;
- Keep all documents safe and accessible in hard copy and electronic format;
- Update the SACAP REC research ethics website; and
- Execute any other tasks assigned to them by the SACAP REC Chair.

## 11. PROCEDURE(S)

- 11.1. The SACAP REC must always be an NHREC registered committee, as well as endorsed by the College.
- 11.2. **Code of conduct for SACAP REC members:** Members of the REC are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. All SACAP REC members will be expected to sign a code of conduct. Over and above this code of conduct, it will be expected of SACAP REC members to:
- 11.2.1. Agree to a term of office of three (3) years;
  - 11.2.2. Familiarise themselves with the institutional documentation as well as national and international research ethics guidelines;
  - 11.2.3. Attend research ethics training sessions to keep abreast with the latest changes in this field (proof of evidence at least once every three years);
  - 11.2.4. Always act with integrity;
  - 11.2.5. Regularly attend SACAP REC meetings;
  - 11.2.6. Be punctual in the attendance of these meetings; and
  - 11.2.7. 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 and letter of appointment to SACAP REC Committee (*See Annexure C of SOP 2: The Selection, Appointment and Functioning of REC Members*).
- 11.3. **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. In this agreement, laid out in Section 6 of the letter of appointment, SACAP REC members declare that they will disclose to the REC Chair any potential COI in the course of duties performed in the service of the

SACAP REC. (See Annexure D 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 to the SACAP REC Chair. All SACAP REC members must declare any actual, potential, or perceived COI relating to the application for ethical approval submitted to the college and recuse themselves from deliberations on the relevant research proposals/projects using the conflict-of-interest declaration form (See Annexure E of SOP 2: The Selection, Appointment and Functioning of REC Members). In such cases, the REC Chair shall have the power to co-opt additional members.

Conflict-of-interest includes the following:

REC members must disclose any relationship, interest, or other circumstances, which could reasonably be perceived as creating an actual, potential, or perceived COI, including the following:

- 11.3.1. **Personal relationships:** the REC member has a personal relationship with the researcher or key personnel of a research proposal under review by the REC;
  - 11.3.2. **Involvement in the research study:** the REC member (including their partner, spouse, or an immediate family member) is the researcher or co-researcher of the research proposal under review by the REC;
  - 11.3.3. **Business relationships/affiliations:** the REC member serves as a trustee, director, officer, owner, or partner of a for-profit entity that could be affected by the outcome of the research proposal under review by the REC; or
  - 11.3.4. **Financial interests:** the REC member has a financial interest that could be affected by the outcome of the research proposal under review by the REC. Financial interests include equity interests (e.g. stock, stock options, or other ownership interests), payment or expectation of payment derived from intellectual property rights (e.g. patent royalties), and payments received from a for-profit entity for consulting or other services.
- 11.4. **Confidentiality:** All SACAP REC members will be required to sign a confidentiality agreement at the annual 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 (See Annexure F SOP 2: The Selection, Appointment and Functioning of REC Members).

## 12. RELATIONSHIP TO NON-AFFILIATED RESEARCHERS

Researchers with no affiliation to the institution (SACAP) can approach the SACAP REC to review and approve their health research proposals. The SACAP REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and has proper expertise and capacity to evaluate the application. A fee will be levied for such a service.

## 13. MECHANISMS FOR REMUNERATION OF REC MEMBERS

SACAP REC members who are employees of SACAP are remunerated for their services as SACAP REC members as part of their formal job descriptions and conditions of employment. Should the services of a member not on the payroll of the College be required (e.g., layperson, legally qualified person, statistician), their services should be viewed as part of service delivery to their community. However, they may be remunerated according to an honorarium negotiated before the appointment, where they are compensated for time, inconvenience, and expenses (TIE principle).

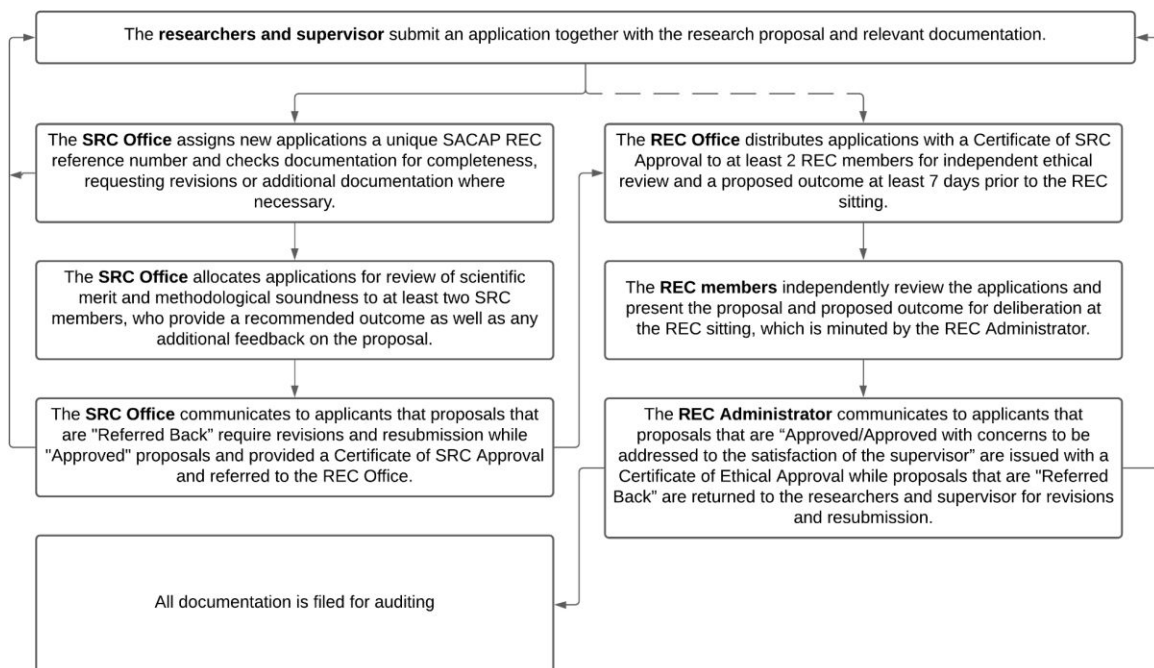
#### 14. TERMS OF OFFICE FOR COMMITTEE MEMBERS

For members who are not employed by the College, the duration of membership tenure for each committee member is three (3) years, in line with the SACAP Research policy and Department of Health (2015) *Ethics in Health Research: Principles, Processes and Structures* guidelines. At the end of a member's term the nomination, election and co-option processes must follow procedures defined in the *Standard Operating Procedures for the Selection, Appointment and Functioning of the SACAP REC*. Members of the SACAP REC may be re-elected or be re-appointed. The list of members will be ratified annually. A committee member can be replaced in the event of resignation from the committee or long-term unavailability.

#### 15. MEETINGS AND QUORUM REQUIREMENTS

SACAP REC sittings are scheduled annually according to the submission dates of SACAP programmes that produce research that requires ethical review. The annual dates of sittings are electronically communicated upon receipt of a signed letter of appointment. However, in cases where urgent applications need to be reviewed, a special meeting may be called. A minimum of simple majority (50% + 1) of the members is required to constitute a quorum. The minutes of the previous meeting will be distributed within seven (7) working days from the date of the meeting. The agenda and all documents relevant to the meeting will be circulated to the members ten (10) working days prior to the date of the meeting.

#### 16. CONSIDERATION AND REVIEW OF RESEARCH PROPOSALS/PROJECTS



Research proposals/projects shall be reviewed for scientific validity by the College Scientific Review Committee (SRC) whilst SACAP REC will review proposals for ethical acceptability as part of its assessment of their ethical awareness, the protection of human rights and social justice.

Each application reviewed for ethical approval of research involving human participants to the SACAP REC will be accompanied by a recommendation letter signed by the SRC Chair that the application and associated documents may proceed to be reviewed by the SACAP REC for ethical approval. Upon receipt the SACAP REC Administrator will screen the documents for completeness. If complete, then

the application for ethical approval will be registered and provided with an ethics reference number. Once the application has received a unique number, the SACAP REC Administrator notifies the SACAP REC Chair about the submission and thereafter distributes them to the respective SACAP REC committee members for review (*See SOP 3: The Protocol Review Process and SOP 4: Proposal Applications and Decisions*). The review process will additionally determine the level risk of the study (*See SOP 17: Risk Assessment*).

Each application reviewed for ethical approval will entail SACAP REC members deliberating on an outcome, and, in case of differing views, the decision will be made based on consensus. In case of consensus not being reached, voting will be used to determine the final outcome. Feedback to the researchers who submitted the proposal for ethical approval will be provided within seven (7) working days after the decision is taken. For high-risk research, researchers will be expected to submit a quarterly report to the SACAP REC Administrator, who will forward it to the SACAP REC Chair to report on it in an official meeting (*See SOP 8: Annual Progress and Monitoring Reports*).

Any adverse events that occur as a direct or indirect result of the research activity must be reported to the SACAP REC Administrator immediately, who will in turn report to the Chair of the SACAP REC within 24 hours. The research will be suspended immediately until all the relevant safety measures have been put in place. In case of liability, the indemnity cover will pay (*See SOP 14: Adverse Events, Serious Adverse Events and Unanticipated Problems*).

## 17. MECHANISMS OF REPORTING AND INSTITUTIONAL LINE OF AUTHORITY

- 17.1. **Complaints Procedure:** The reporting lines of the RECs registered at the NHREC require additional reporting lines required by the National Health Act, No. 61 of 2003. Should a researcher/postgraduate student experience a problem with a specific SACAP REC member's behaviour or the SACAP REC itself regarding meeting procedures, application management or reviewer report(s), they have the opportunity to lodge a complaint. The complaint should be lodged in writing to the REC Chair via the REC Administrator. The procedure of such a complaint should follow the line of communication as stipulated (*See SOP 15: Complaints Procedures*). Should the complaint remain unresolved, the complainant could then approach the Academic Dean. Should the complaint remain unresolved, the complainant could then approach the NHREC.
- 17.2. **Whistleblowing:** Additionally, the SACAP REC makes provision for whistleblowing, which is the act of informing the SACAP REC Chair about alleged research misconduct (fabrication, falsification, or plagiarism), fraud, maladministration, and non-adherence to approved research procedures, guidelines or policies occurring at the SACAP. Whistleblowing deals only with alleged actions committed by researchers (employees and/or students of SACAP) within the ambit of research with respect to human participants, or environmental impact. In the case of research related concerns and irregularities, whistle-blowers may submit a whistleblowing form on the SACAP website in the dedicated whistleblowing section. The whistle-blower form makes provision for whistle-blowers to report the details surrounding the alleged concern and may additionally choose to remain anonymous. All reports are forwarded to the SACAP REC so that issues that have been reported can be followed up and investigated in accordance with the approved procedures (*See SOP 16: Whistleblowing Pertaining to Research*).

**18. REFERENCE DOCUMENTS**

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- Regulations Relating to Research with Human Participants, 19 September 2014.
- The Belmont Report, 1979.
- The Code of Federal Regulations of the USA (Title 45 Part 46).
- The Declaration of Helsinki, 2013.
- The International Conference on Harmonization: Good Clinical Practice (ICH-GCP), 1997.
- The National Health Act, No. 61 of 2003.
- The Singapore Statement on Research Integrity, 2010.