TERMS OF REFERENCE, DECEMBER 2024, V4

South African Medical Association Research Ethics Committee (SAMAREC)

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1. ACRONYMS AND DEFINITIONS

ACRONYM	DEFINITION
Board	Shall mean, the Board of Directors of The South African Medical Association Non-Profit Company (NPC)
Company	Shall mean, The South African Medical Association NPC
Committee /SAMAREC	Shall mean, the South African Medical Association Research Ethics Committee
Officer Bearer	means, any individual who holds a position on a The South African Medical Association NPC structure, i.e. Board, Committee, Branch etc and who is not a SAMA staff member.
SAMA	means, The South African Medical Association NPC
Term	means, 3-year period
ToR	Terms of Reference

Words importing the singular will include the plural, words importing the masculine, feminine or neuter will include the others of such genders, and words importing persons will include bodies corporate, and vice versa in each instance.

2. NAME OF COMMITTEE

The name of the Committee is the South African Medical Association Research Ethics Committee *SAMAREC is a Committee duly registered with the National Health Research Ethics Council as required by Section 73 of the National Health Act, Act No 61 of 2003.*

3. PURPOSE

3.1. To evaluate the ethics of research protocols developed for clinical trials to be conducted in the Private Healthcare Sector, in terms of national and international regulatory requirements, which require all health research involving human participants must undergo an independent ethics review.

3.2. Provide an independent and objective appraisal of the research proposal as it affects the prospective participants and the general day-to-day functioning of the health system.

4. AUTHORITY

4.1. The Committee functions within the legislative framework of the National Health Act, 61 of 2003, as amended, (NHA) and as such is registered with the Department of Health (DOH) National Health Research Ethics Council (NHREC).

4.2. While the Committee is a structure of the Company, it operates independently without any interference from the Board, and with no external pressure to the members regarding any decisions reached as the Committee has the authority and legal accountability for the evaluation and approval of ethically acceptable research proposals.

4.3. In the execution of its responsibilities in evaluating the ethics of research protocols, the Committee is guided by the relevant South African law, research and ethics guidelines, professional standards, international standards and guidelines and codes of practice.

4.4. The Committee follows the standards adopted by the latest version of the Food and Drug Administration (FDA) and The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice; and conforms to the guidelines laid down by the World Medical Association, in particular, the Declaration of Helsinki (updated Oct 2024), the Belmont Report, the National Department of Health's Ethics in Health Research: Principles, Structures and Processes (2024), the South African Health Products Regulatory Authority (SAHPRA) and other relevant statutory bodies involved in the healthcare sector.

5. RESPONSIBILITIES OF SAMAREC

5.1. The primary role of the Committee is to protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research.

5.2. The Committee will provide assurance to the public of participants' protection, *inter alia* by reviewing, approving, providing comment on clinical trial protocols, the suitability of investigator(s), facilities, methods, and procedures used to obtain informed consent, and the monitoring of clinical research.

5.3. The Committee reviews health research involving human participants, prior to the initiation of such research and focuses on the ethical implications relating to the clinical research.

5.4. The Committee will advise and/or make suggestions to study doctors and applicants, when requested to do so.

5.5. The Committee should consider the following issues when reviewing a proposal for a clinical study: Please refer to the SAMAREC Induction Standard Operating Procedure (SOP) and SAMAREC Minutes SOP.

5.5.1. the scientific validity and relevance of the clinical study;

5.5.2. the suitability of the investigator(s) for the proposed study in terms of his/her availability, qualifications, experience, support staff, and available facilities;

5.5.3. the relevance of the study rationale and the appropriateness of the inclusion/exclusion criteria to the South African context;

5.5.4. the suitability of the study application in relation to the objectives of the study; i.e. the potential for reaching sound conclusions with the smallest possible exposure to risk of participants, and the justification of predictable risks and inconveniences weighed against the anticipated benefits for the participants and/or others;

5.5.5. the suitability of the study population, whether they constitute a vulnerable group, if so, whether justified and whether sufficient measures to protect their interests are in place;

5.5.6. that the number of participants to be recruited is adequate in order to demonstrate the predicted effect;

5.5.7. the risk-benefit analysis takes full cognisance of benefits and harms beyond the life of the study itself, particularly in relation to chronic life-threatening conditions;

5.5.8. if placebos are to be used, whether their use can be justified;

5.5.9. that by their participation in a clinical study the participants are not denied timely access to medical personnel, investigations, equipment or procedures;

5.5.10. the means by which initial recruitment is to be conducted and by which full information is to be given and how informed consent is to be obtained;

5.5.11. the adequacy and completeness of the written information to be given to the participants, their relatives/guardians and, if necessary, legal representatives. All written information for the participant and/or legal representative must be submitted in its final form;

5.5.12. that the application allows the participants and/or their representatives adequate time to consider the patient information document before informed consent is sought;

5.5.13. the content of any advertisements or public notices which will be used to recruit participants to a study;

5.5.14. the study protects participants' rights to privacy and confidentiality;

5.5.15. the provision of compensation/treatment in the case of injury or death of a participant if attributable to a clinical study, and the insurance or indemnity to cover the liability of the investigator and sponsor;

5.5.16. the extent to which investigator(s) and participants are to be compensated for participation in the study;

5.5.17. making specific recommendations regarding the continuation of treatments beyond the duration of the study, or mechanisms to ensure that participants' access to treatment are fairly protected and not unduly compromised;

5.5.18. the demographic information available to assess whether the patient population is adequate to support the study;

5.5.19. whether there is no cost to the participant, medical schemes or insurance for trial specific procedures;

5.5.20. whether the product will be made available to participants after the trial ends, and if so whether there is any cost to the participant to continue treatment post-trial;

5.5.21. whether any restrictions will be placed on the publication of results by the investigators after completion of the trial; and

5.5.22. the adequacy of the statistical methods proposed to evaluate the data generated; and whether the study is advancing knowledge in the research field.

6. MEMBERSHIP

6.1. Composition

6.1.1. SAMAREC should be independent, multi-disciplinary, multi-sectoral and pluralistic.

6.1.2. Collectively, the Committee should include sufficient members with the necessary qualifications and experience, including research ethics training, to be able to review and evaluate the science, the health aspects, the ethics of the proposed research, as well as to assess the anticipated layperson's perspective.

6.1.3. The Committee may co-opt and appoint additional members, based on the requirements of the Committee. This decision may be left to the SAMAREC Committee in order to avoid conflicts of interest.

6.1.4. Co-opted members will not be regarded as full members. For avoidance of doubt, the co-opted members will not be entitled to voting rights, benefits and the accrual of full responsibilities as an appointed member of the Committee.

6.1.5. The Committee should consist of:

6.1.5.1. at least one layperson;

6.1.5.2. at least one member with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people. Examples of suitable experience for such a portfolio include *inter alia that of* a medical practitioner, psychologist, social worker or nurse;

6.1.5.3. at least one member with professional training and experience in qualitative research methodologies;

6.1.5.4. members with professional training and experience in quantitative research methodologies;

6.1.5.5. a member with expertise in bio-statistics;

6.1.5.6. a member with expertise in research ethics; and

6.1.5.7. at least one member who is legally qualified.

6.1.5.8. a member who represents the vulnerable community

6.1.7. Members shall not be drawn not only from the senior ranks.

6.1.8. Membership of the Committee shall be ethnically and culturally diverse members; with not more than 70% members being either male or female.

6.1.9. The recruitment process will involve being invited to attend a meeting for an interview and to remain as an observer.

6.1.10. Once the Committee has decided to elect the new member, the Committee member will attend as an observer for another 2 months and will subsequently be allocated protocols once the relevant training has been completed

6.2. Committee Terms of Appointment

6.2.1. Members shall be appointed for a term which shall be served for 5 years.

6.2.2. A member of the Committee, appointed per the procedures set out (or co-opted as per the relevant instance), will only hold office until the end of the current term.

6.2.3. A term of office begins on the day the member has been appointed. A renewal of appointment letter will be circulated annually. This will also be applicable in cases for the appointment for a consecutive term.

6.2.4. No Committee member may serve for more than (2) consecutive terms in office.

6.2.5. A Committee member who has exceeded the aggregate term to act as a Committee member may again become eligible for appointment to the Committee after **not** having served on the Committee for one (1) term.

6.3. Rotation of Committee members

6.3.1. Where possible (without contravening section 6.1.6) one third (1/3) of the Committee members must stand down from office, every three (3) terms. If the number of Committee members is not three or a multiple of three, the number nearest to one-third (1/3), rounded down, stands down from office.

6.3.2. Committee members who stand down as part of the rotation process may stand for re-appointment, provided they are eligible to do so.

6.3.3. Co-opted Committee members must stand down from office, at the end of the term in which they were co-opted and are not counted when calculating the one third (1/3) of elected Committee Members expected to stand down.

6.3.4. The Committee members expected to stand down will be those who have been longest in office since the last appointment. In the event of two or more Committee members having been in office for the same length of time and only certain of these Committee members being required to stand down, the Committee members concerned, may either between themselves, agree or utilise the method of drawing lots.

6.4. SAMAREC Members Remuneration

6.4.1. SAMAREC members will be remunerated in accordance with the SAMA Honorarium Policy and rates.

6.4.2. Committee members who are not SAMA employees are remunerated according to the SAMA Honorarium Policy and rates.

6.5. Termination and Vacancies

6.5.1. A Committee member must vacate office if:

6.5.1.1. the Board approves a recommendation to remove the member in line with the Company's Office Bearers' Conduct and Removal Policy, for breach of any of the conduct standards and expectations set out therein. This includes but is not limited to attendance, participation, performance, communication and conduct;

6.5.1.2. the member is found to be of unsound mind by a court of law;

6.5.1.3. the member is found guilty of materially breaching SAMA's Code of Conduct; or reported via the SAMAREC Whistleblower form available on the SAMAREC Website and included in the SAMAREC SOP;

6.5.1.4. the member is no longer registered with SAMA as a member, if applicable;

6.5.1.5. In the application of Clause 6.2.5 herein.

6.5.2. In the event of a termination of membership or the creation of any vacancy, the position on the Committee will be filled by co-opting members in terms of clause 6.1 above. This will be done immediately once a vacancy becomes available. SAMAREC must commit to having potential trained new members available for when such need arises.

6.5.3. If the position of the Committee Chairperson becomes vacant, the Vice-Chairperson will take up the position of Committee Chairperson immediately.

6.5.4. If the position of Committee Vice-Chairperson becomes vacant, the Committee will appoint a new Vice-Chairperson from amongst the current Committee members.

7. POWERS AND DELEGATION OF POWERS

7.1. In respect of the objectives and activities of the Committee, the Committee will report to the Board, through the South African Medical Association's Education Science and Technology Committee.

7.2. The SAMAREC Committee may in writing request any SAMA staff member to perform any of the duties assigned to the Committee when necessary.

7.3. An instruction to a SAMA staff member is subject to any limitations and conditions that the Committee may impose and does not divest the Committee of their responsibility concerning the performance of the assigned duties.

7.4. The Committee may confirm, vary or revoke any action taken by a SAMA staff member as a result of an instruction, subject to any rights that may have become vested as a consequence of the decision.

8. CULTURE AND INTERPERSONAL DYNAMICS

8.1. The Committee contains a collection of diverse minds that need to speak as one voice and therefore requires Committee members to be mindful of the diversity and differences of fellow Committee members.

8.2. Committee members will treat each other with mutual respect at all times.

8.3. Any form of racism or sexism will not be tolerated.

8.4. Openness and equality between Committee members is essential.

8.5. Debates on critical issues should be brought to a clear and consensual conclusion.

8.6. Threats and intimidation of any kind will not be tolerated.

8.7. SAMA is not affiliated to any political party of the Republic of South Africa, and it is the intention of SAMA not to affiliate or allow undue influence from political parties. Whilst SAMA respects the views and personal participation of the Committee members in the political process, Committee members are to align with this principle whilst performing the duties and responsibilities of a Committee member.

9. MEETINGS

9.1. Frequency of meetings

9.1.1. The Committee will meet on the second Wednesday of each month, unless any unforeseen consequences require otherwise e.g., the foreseeable failure to reach quorum.

9.1.2. The meeting dates for the year will be disseminated to the Committee members as close to the beginning of every calendar year as possible.

9.1.3. Any member of the Committee may request a meeting if deemed necessary and a meeting may then be arranged in consultation with the Committee Chairperson, should the request be a reasonable one.

9.2. Agendas and minutes

9.2.1. The SAMAREC Officer will, among others, draft an agenda, compile and circulate the meeting pack 10 (ten) working days prior to the scheduled meeting. The meeting pack shall consist of all applications and other supporting documents, as well as a protocol evaluation form for each application. The meeting pack will be distributed to members by the SAMAREC Officer in accordance with the timeframe contained in this section..

9.2.2. All input must be received at least 2 (two) days prior to the scheduled meeting. All input received from the Committee Members is collated by the SAMAREC Officer. Committee Members are to use the Standard SAMAREC Evaluator Document for all protocol evaluations. The input received is discussed at the formal meetings of the Committee.

9.2.3. Minutes are circulated 1-3 working days after the meeting to the Committee Members. The entire Committee is tasked with reviewing the minutes. The main evaluators for each protocol must take responsibility for the correction or approval of the minutes of their allocated protocols. After final approval of the minutes has been granted by all the Committee Members, to whom the minutes are circulated electronically, extracts of the minutes are distributed to the relevant clients in the form of a formal letter.

9.2.4. A written response regarding decisions is usually forwarded to applicants within 10 (ten) working days after the meeting.

9.2.5. The official minutes will consist of those duly signed by the Committee Chairperson.

9.3. Approvals

9.3.1. Approvals of the Committee will be made by support of 50% plus 1 of the Committee members present at the Committee meeting.

9.3.2. In the event of an equality of votes on any matter, the Committee Chairperson will have an additional casting vote.

9.3.3. A written approval (round robin approvals) signed by 50% plus 1 of the Committee members will be as valid and effectual as if it has been passed at a duly constituted meeting of the Committee, provided that each

Committee member will have been afforded seven (7) working days opportunity to express an opinion on the matter to which such approval relates.

9.3.4. Once a written approval has been approved, it may not be challenged or impugned by any person in any forum on the grounds that it did not satisfy clauses 9.3.1, 9.3.2 and 9.3.3 above.

9.4. Quorum and postponement

9.4.1. A quorum for meetings of the Committee will be 60% plus 1 of the Committee members.

9.4.2. Quorum cannot consist of only members of the same field, race or gender.

9.4.3. Quorum must include at least one member with a non-scientific background.

9.4.4. If the Committee Chairperson is not present within ten (10) minutes of the stipulated start time for such meeting, the Vice-Chairperson will act as Chairperson of the meeting.

9.4.5. If neither the Committee Chairperson or Vice-Chairperson is present within ten (10) minutes of the stipulated start time for such meeting, Committee members present will elect a Chairperson from their own ranks to act as the Chairperson of the meeting.

9.4.6. If after fifteen (15) minutes of the stipulated time for such meeting to commence, quorum has not been met, the Chairperson may, without obtaining consent of those present at the meeting, declare that the meeting be postponed for one week (7 calendar days).

9.4.7. If at the time appointed for the postponed meeting to begin, the requirements of clause 9.4.1 have not been satisfied, the members of the Committee present will be deemed to constitute quorum.

9.5. Attendance and apologies

9.5.1. Any SAMA Executive Committee (ExCo) or staff member may be invited to attend a Committee meeting, when necessary. Such instances may involve general oversight by the SAMA Board or when the relevant expertise or opinions are needed from the external party, e.g., legal advice.

9.5.2. The Committee may in consultation with the Committee Chairperson, invite any other relevant person to attend Committee meetings. Reasonable examples of such instances include *intera alia* to co-opt expertise or to invite a potential new SAMAREC Member. All relevant conflict of interest and Code of Conduct documentation must be completed prior to attendance.

9.5.3. Invitees will be entitled to be reimbursement for time, travel or other expenses related to their attendance of meetings, as per SAMA's approved policies.

9.5.4. Invitees are authorised to participate in any deliberations of the Committee but shall have no voting rights.

9.5.5. Invitees do not count for the purposes of calculating quorum of a meeting.

9.5.6. The Committee may, if deemed fit, confer, and meet by telephone, closed circuit television, electronic online conference meeting platforms or video conferencing. Decisions taken at such meeting/s will constitute a proper decision of the Committee provided that the requirements of clause 9.3 and 9.4 of this Terms of Reference document have been met.

9.5.7. All Committee members have an obligation to attend all Committee meetings.

9.5.8. Committee members must communicate to the Committee Chairperson and/or relevant meeting organiser, their unavailability to attend an upcoming meeting no later than three (3) days before the meeting to give the Chairperson enough time to decide on the continuation/postponement and/or the impact of the Committee members' unavailability on the agenda of the upcoming meeting.

9.5.9. In circumstances beyond the control of the Committee member, such as unexpected situations or emergencies, apologies may be accepted via telephone call, SMS, WhatsApp or email forwarded to the

Committee Chairperson and/or relevant meeting organiser of the meeting, up to 1 (one) hour prior to the meeting.

9.5.10. In the event that no apology is recorded for a meeting, the Committee member will be recorded as absent.

10. REPORTING ACCOUNTABILITY

10.1. The Committee Chairperson will report formally to the Board on the Committee's proceedings quarterly on all matters within the ambit of the Committee's duties and responsibilities, through the South African Medical Association's Education Science and Technology Committee.

10.2. The Committee will produce a report on its activities to be included in the Company's annual report.

10.3. The Committee Chairperson will attend the Annual General Meetings of the Company and shall be prepared to respond to any member questions on the Committee's activities.

10.4. The Committee will produce a report on its activities annually, to be submitted to the NHREC on or before 28 February of each year, which report must include:

10.4.1. membership and membership changes;

10.4.2. the number of meetings held;

10.4.3. confirmation of participation by required categories of members;

10.4.4. the number of protocols presented, the number approved, and the number rejected;

10.4.5. monitoring and related matters; and

10.4.6. complaints received and action taken.

11. ROLES AND RESPONSIBILITIES OF MEMBERS

11.1. Appointment of Committee Chairperson and Vice-Chairperson

11.1.1. The Committee Chairperson and Vice-Chairperson will be elected by the members of the SAMAREC Committee, at the first meeting of any new term. The Committee members will nominate the new Chairperson and vote accordingly.

11.1.2. If the position of Chairperson of the Committee becomes vacant, the Vice-Chairperson of the Committee will automatically become Chairperson of the Committee.

11.2. Role of the Committee Chairperson

11.2.1. The primary role of the Chairperson of the Committee is to provide leadership to the Committee, set the tone for its performance and undertake the management thereof.

11.2.2. The Chairperson of the Committee ensures that focus is maintained by the Committee and sets the tone for the success of the Committee.

11.2.3. The Chairperson guides Committee members to participate as a cohesive and effective team.

11.2.4. The Committee Chairperson shall create awareness with Committee members' in order for a mutual understanding of roles, responsibilities and accountability, including the need to comply with the Code of Conduct.

11.3. Chairperson's responsibilities and duties

The Committee Chairperson's responsibilities are to:

11.3.1. Provide overall leadership to the Committee.

11.3.2. Oversee that the Committee leads ethically and effectively, and that the Committee conducts itself in a way that cultivates and exhibits the characteristics of integrity, competence, responsibility, accountability, fairness and transparency.

11.3.3. Maintain that the Committee and its decisions are not influenced by any third party, including any political parties of the Republic of South Africa.

11.3.4. Oversee that conflicts of interest, including policy declarations and recusal are addressed appropriately.

11.3.5. Preserve order and quorum, voting procedures, adjournments and to declare outcomes of voting on approvals.

11.3.6. Monitor the progress of the meeting in terms of allocated time, objectives of the meeting and progress of agenda items.

11.3.7. Ensure that agenda items receive appropriate attention, and that the discussion of the agenda item remains relevant to that particular item as well as with the objectives of the meeting.

11.3.8. Ensure that Committee members have an opportunity to provide an opinion, possible recommendations or concerns thus facilitating all-around participation.

11.3.9. Encourage robust and productive debate as well as to ensure interactive participation by all Committee members, without inhibiting candid debate and creative tension.

11.3.10. Encourage all Committee members to adhere to professional courtesy and conduct at all times as well as encourage Committee members to illustrate the necessary respect regarding the importance of professional time.

11.3.11. Ensure the Committee performs the responsibilities and duties as legislatively assigned.

11.3.12. Review draft minutes of Committee meetings before finalisation and distribution to Committee members.

11.3.13. Ensure that the responsibilities of the Committee as well as the Committee members are understood by all Committee members.

11.3.14. Ensure that new Committee members are appropriately made aware of their responsibilities.

11.3.15. Ensure clarity on the Committee's authorities and the resources allocated to the Committee.

11.3.16. Be reasonably available to individual Committee members, staff members who are designated as a resource to the Committee and/or external advisors to SAMA for discussion and/or consultations on matters related to the Committee.

11.3.17. Review protocol deviations and violations.

11.3.18. Review Adverse reaction reports.

11.4. Roles and Responsibilities of the Secretariat/SAMAREC Officer

11.4.1. Organise effective and efficient tracking procedures for each received proposal or protocol.

11.4.2. Prepare and maintain application documents and meeting packs.

11.4.3. Organise regular Committee meetings.

11.4.4. Prepare, distribute, and maintain meeting agendas and arrange meeting logistics.

11.4.5. Maintain and archive documentation.

11.4.6. Provide the necessary administrative support for Committee-related activities of the Committee, the Chairperson of the Committee and Committee members.

11.4.7. Perform a pre-review of each submission to ensure adherence to administrative requirements.

11.4.8. Properly acknowledge, distribute, and keep files of all correspondence.

11.5. General Roles and Responsibilities of Committee members

11.5.1. Committee members accept their appointment as members and in so doing demonstrate an active interest in the Committee. This entails a willingness to serve (commitment), an ability to serve (time), valuable contribution (knowledge and skill), professional reputation (ethical and cooperative) and reliability (will assume the necessary responsibilities) as well as leadership and communication skills.

11.5.2. The primary responsibility of each Committee member is to decide independently whether the proposed research protects the interests of participants adequately and adheres to exemplary standards in research activities.

11.5.3. The Committee acknowledges that the success of the Committee depends on the contributions made by each of its members. In general, their responsibilities and duties include:

11.5.3.1. Being well-informed of the responsibility and duty of a Committee member;

11.5.3.2. Attendance of all meetings;

11.5.3.3. Becoming familiar with the history, current remit, and the other members of the Committee;

11.5.3.4. Review of the agenda and accompanying materials *prior* to attending the meeting, to provide appropriate and constructive input on matters tabled at meetings and seeking clarification of any items that are not clear;

11.5.3.5. Reading through the meeting supplement folder prior to the meeting;

11.5.3.6. Following the agenda and discussion during the meeting;

11.5.3.7. Determining what the exact purpose of the meeting is and deciding in advance how and what to contribute;

11.5.3.8. Keeping replies short and to the point;

11.5.3.9. Participating actively in meetings via comment or constructive criticism or disagreement;

11.5.3.10. Keeping in mind that the Committee as a whole, has authority and not its individual members;

11.5.3.11. Assisting with and sharing the work of the Committee in fulfilling its mandate;

11.5.3.12. Adherence to professional courtesy and conduct at all times as well as illustrating the necessary respect regarding the importance of professional time;

11.5.3.13. Maintaining responsibility and accountability for tasks assigned by the Committee;

11.5.3.14. Maintaining characteristics of integrity, competence, fairness, and transparency;

11.5.3.15. Abiding by the Officers Bearers' Code of Conduct;

11.5.3.16. Ensuring that reviews are done objectively, independently, and impartially as to ensure that the patients' welfare, rights, and safety is ensured;

11.5.3.17. Ensuring that the Standard SAMAREC Review Document is used in all evaluations;

11.5.3.18. Ensuring that all evaluator input is forwarded to the Committee Co-ordinator at least 1 (one) working day before the formal meeting

11.5.3.19. The review meeting minutes once distributed by the SAMAREC Officer; and

11.5.3.20. That new members are appointed in accordance with the DOH Guidelines and requirements of the Committee and the studies evaluated.

12. RESOURCES AND BUDGET

12.1. The Committee will have access to sufficient resources in order to carry out its duties.

12.2. The Committee is authorised to seek information from any employee of SAMA in order to perform and achieve its objectives as set out in the Committee's Terms of Reference, provided that the lines of communication, as set out in the SAMA Communications Policy, are adhered to.

12.3. The Committee is allowed to obtain, at SAMA's expense, outside legal or other professional advice on any matters within its Terms of Reference, provided that:

12.3.1. the Head of Department (HOD): Legal is consulted on all legal matters and supports the Committee's request for external legal advice;

12.3.2. due regard is observed to overall budget constraints;

12.3.3. the Committee obtains the Board's *prior* approval regarding any suggested outside advice is obtained, before such service is procured; and

12.3.4. the procurement of such service is subject to the procurement and other policies of SAMA being followed in this regard.

12.4. The Committee requirement for ad hoc or specialist consultants for specific protocols will be assessed on a case-by-case basis.

12.5. The Committee may request other individuals to assist in the review of complex issues outside the expertise of the members, but such individuals may not vote on matters requiring a decision to be taken; These individuals will also only be approached should they not have a conflict of interest in the study in question and will also be required to sign a confidentiality agreement. These individuals will be approached based on a referral basis.

12.6. The Committee will operate within the limits of its budget, as approved by Board.

12.7. Committee members who are SAMA employees are not remunerated for their services as members; this is to ensure that the risk of conflict of interest is reduced and that members are able to be objective in the functioning of their duties.

13. RELATIONSHIP TO NON-AFFILIATED RESEARCHERS AND OTHER STAKEHOLDERS

13.1. The Committee deals with research conducted in the Private Healthcare Sector and is not affiliated with any researchers. Therefore, any researcher within the Private Healthcare Sector may approach the Committee to review their research proposals, approvals for which will be done on a case-by-case basis.

13.2. In the event that specific matters under the authority of the Committee warrant a referral and/or collaboration with other Committees, the Committee is authorised to make such referrals and/or facilitate such collaborations.

13.3. Any communication by the Committee directed at SAMA members and/or other stakeholders will be carried out in terms of the SAMA Communications Policy.

14. REVIEW

14.1. The Committee will review these Terms of Reference as required and recommend to the Board such revisions as the Committee may believe to be required by new laws or to be prudent.

15. EVALUATION

15.1. The Committee will conduct a self-assessment or self-evaluation of its effectiveness on an annual basis.

16. DATA STORAGE

16.1. For the effective management and review of protocols and research proposals submitted to the SAMA Research Ethics Committee (SAMAREC), all documents will be uploaded and stored on Microsoft SharePoint. This platform allows for efficient collaboration while maintaining strict confidentiality. Microsoft SharePoint is equipped with robust security features, including encryption, access controls, and multi-factor authentication, ensuring that only authorised SAMAREC members have access to sensitive information. This secure system provides a safe and confidential environment for reviewing ethical submissions, safeguarding the privacy of the data in compliance with ethical and regulatory standards.

16.2. In addition to being uploaded and stored on Microsoft SharePoint for review, all protocols and research proposals submitted to the SAMA Research Ethics Committee (SAMAREC) will also be backed up on the SAMA P Drive server. This dual storage approach ensures an additional layer of security and data protection, with the P Drive serving as a reliable backup system. Both storage systems are protected by advanced security protocols, including encryption and access control, ensuring that sensitive information remains confidential and secure at all times. This redundancy guarantees that data will be preserved and accessible, even in the event of technical issues

17. TRAINING

17.1. Committee members should receive a complete orientation that allows them to function effectively from appointment.

17.2. Committee members and researchers are expected to familiarise themselves with national and international research ethics guidelines and should have documented proof of such familiarity.

17.3. Opportunities for continuous education and training in research ethics and Good Clinical Practice should be actively pursued by each Committee member and members are expected, at least once during each year of appointment, to produce evidence of recent training.

17.4. Committee members who review clinical trial proposals should have Good Clinical Practice training, evidenced by a certificate issued not more than 2 years previously.

17.5. SAMAREC will supplement the training of any SAMAREC member where necessary e.g., through relevant conferences and training.

17.6. Online training opportunities shall also be made available to members.

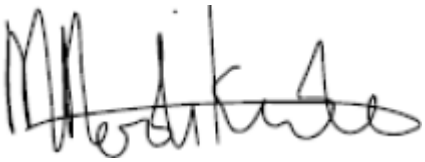
Approved by:

Dr N Naidoo

SAMAREC Chairperson

Date: 24 February 2025

Endorsed by:



Dr M Nodikida

SAMAREC CEO

Date: 27 February 2025