



APPEALS AGAINST RESEARCH ETHICS COMMITTEE DECISIONS SOP, JULY 2026, V1

Research Ethics
Committee

Final Version	Reason for Amendment	Effective Date
1	Updated and published for implementation	July 2026
	Administrative changes	July 2026

1. PURPOSE

The purpose of this section is to establish a fair, transparent, and consistent process through which applicants may request reconsideration of decisions made by the South African Medical Association Research Ethics Committee (SAMAREC). This procedure seeks to ensure that all applicants are afforded procedural fairness and an opportunity to challenge decisions where there are legitimate grounds for appeal, while maintaining the independence and integrity of the ethical review process.

This procedure is guided by the National Health Act 61 of 2003, the National Health Research Ethics Council (NHREC) Guidelines and Registration Requirements, the Department of Health's *Ethics in Health Research: Principles, Processes and Structures (2024)*, and the principles of lawful, reasonable, and procedurally fair administrative action as contemplated in the Promotion of Administrative Justice Act 3 of 2000.

2. SCOPE

- 2.1 This procedure applies to all researchers, sponsors, institutions, and applicants whose protocols, amendments, continuing review applications, or other submissions have been reviewed by SAMAREC and who wish to appeal a decision made by the Committee.
- 2.2 This procedure applies to decisions including, but not limited to:
 - Rejection of a research protocol;
 - Conditional approval where the applicant disputes the conditions imposed;
 - Suspension of ethical approval;
 - Withdrawal or termination of ethical approval;
 - Refusal of protocol amendments;
 - Decisions relating to serious or continuing non-compliance; and
 - Any other decision materially affecting the conduct of an approved or proposed research study.

3. PRINCIPLES GOVERNING APPEALS

- 3.1 The appeal process shall be governed by the principles of independence, impartiality, transparency, procedural fairness, accountability, and consistency.
- 3.2 An appeal shall **not** constitute a new ethics review but shall be limited to consideration of the grounds upon which the original decision is challenged.
- 3.3 The lodging of an appeal shall not automatically suspend the operation of the decision under appeal unless expressly determined by the Chairperson or the Appeals Committee.

4. GROUNDS FOR APPEAL

An appeal may be lodged on one or more of the following grounds:

4.1 Procedural Irregularity

Where the applicant reasonably believes that the review process was not conducted in accordance with applicable laws, regulations, SAMAREC Standard Operating Procedures, or principles of procedural fairness.

4.2 Material Error of Fact

Where the decision was based on incorrect, incomplete, or materially inaccurate factual information which may have influenced the outcome of the review.

4.3 New Evidence

Where significant new information or evidence becomes available after the decision was made and such information could not reasonably have been submitted during the original review process.

4.4 Misapplication of Ethical or Regulatory Standards

Where the applicant reasonably believes that applicable ethical principles, guidelines, legislation, or regulatory requirements were incorrectly interpreted or applied.

4.5 Disproportionate Decision

Where the applicant believes that the decision reached is unreasonable or disproportionate in relation to the ethical concerns identified.

4.6 Conflict of Interest or Bias

Where there is credible evidence that an undisclosed conflict of interest, bias, or perceived bias may have materially affected the decision-making process.

5. EXCLUSIONS

An appeal shall not be entertained solely on the basis that the applicant disagrees with the Committee's ethical judgment or scientific assessment where no grounds contemplated in Section 4 have been established.

The submission of substantially revised protocols shall ordinarily be treated as new submissions rather than appeals.

6. APPEAL SUBMISSION PROCESS

An appeal must be submitted in writing to the SAMAREC Secretariat within thirty (30) calendar days of the applicant receiving notification of the decision.

The appeal submission must contain:

- The study title and protocol number;
- The decision being appealed;

- Detailed grounds for appeal;
- Supporting documentation and evidence;
- Any new information relied upon; and
- The specific relief sought by the appellant.

Appeals submitted outside the prescribed period may only be considered upon written application showing good cause for the delay.

7. PRELIMINARY REVIEW OF APPEAL

Upon receipt of the appeal, the Secretariat shall acknowledge receipt within five (5) working days.

The Chairperson, or a delegated senior member not directly involved in the original review, shall conduct a preliminary assessment within ten (10) working days to determine whether:

- The appeal falls within the scope of this procedure;
- Valid grounds for appeal have been established; and
- Sufficient supporting information has been provided.

Where the appeal is incomplete, the appellant may be requested to provide additional information within ten (10) working days.

8. ESTABLISHMENT OF AN APPEALS PANEL

Where an appeal is accepted for consideration, the Chairperson shall appoint an Appeals Panel consisting of not fewer than three (3) members.

The Appeals Panel may include independent external experts where specialised expertise is required.

All members of the Appeals Panel shall declare any actual, potential, or perceived conflicts of interest before participating in the appeal process.

9. CONSIDERATION OF THE APPEAL

The Appeals Panel shall review:

- The original application;
- The decision under appeal;
- The grounds of appeal;
- Any additional evidence submitted;
- Relevant ethical guidelines, legislation, and regulatory requirements.

The Appeals Panel may:

- Request additional information;
- Seek expert advice;
- Invite written representations from the appellant; or
- Where necessary, invite the appellant to make oral submissions.

The Appeals Panel shall not conduct a *de novo* review unless exceptional circumstances justify such reconsideration.

10. DECISION OF THE APPEALS PANEL

The Appeals Panel shall decide within thirty (30) calendar days of receiving a complete appeal submission, unless exceptional circumstances justify an extension.

The Appeals Panel may:

- Uphold the original decision;
- Modify the original decision;
- Set aside the original decision and substitute it with a new decision;
- Refer the matter back to SAMAREC for reconsideration with specific recommendations; or
- Require additional conditions to be met prior to approval.

The decision shall be communicated to the appellant in writing and shall include reasons for the decision.

11. FINALITY OF DECISION

The decision of the Appeals Panel shall be final within SAMAREC's internal processes.

Nothing in this procedure shall preclude an applicant from exercising any rights available under applicable legislation, including referral to the National Health Research Ethics Council where permitted by law, or seeking any other lawful remedy available under South African law.

12. RECORD KEEPING

The Secretariat shall maintain complete records of all appeals, supporting documentation, deliberations, recommendations, and decisions.

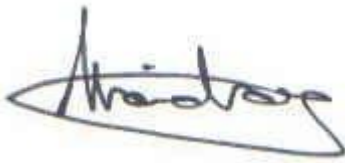
Appeal records shall be retained in accordance with SAMAREC record retention policies, applicable legal requirements, and NHREC guidelines.

13. TIMELINES SUMMARY

- SAMAREC Secretariat acknowledgement of appeal: within five (5) working days.
- Preliminary assessment of appeal: within ten (10) working days.
- Submission of additional information (if requested): within ten (10) working days.
- Final determination of appeal: within thirty (30) calendar days of receipt of a complete appeal submission.

Any deviations from these timelines must be communicated to the appellant together with the reasons for the delay.

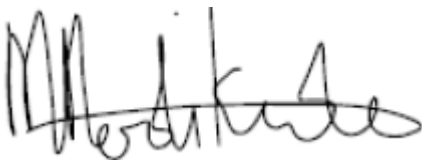
Approved by:

A handwritten signature in black ink, appearing to read "Naidoo", enclosed within a hand-drawn oval.

Dr N Naidoo

SAMAREC Chairperson

Date: 14/06/2026

A handwritten signature in black ink, appearing to read "M Nodikida", written in a stylized, cursive script.

Dr M Nodikida

SAMAREC CEO

Date: 26 June 2026