THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
ETHICS COMMITTEE FOR RESEARCH ON ANIMALS (ECRA)
TERMS OF REFERENCE

1. PREAMBLE

The South African Medical Research Council (SAMRC) recognises the moral dilemma posed by the use of sentient animals (i.e. animals which can feel sensations and experience emotions) for research, teaching and testing. It subscribes to the ethics of supporting studies which pledges to contribute to the scientific understanding of biology, environmental principles and the acquisition of knowledge that can reasonably be expected to benefit humans, animals or the environment.

It recognises that all vertebrate animals are protected by law in South Africa (Animals Protection Act No. 71 of 1962) and that it may be an offence in terms of this law to kill or interfere with the well-being of an animal for scientific or educational purposes without justification which is approved by a formal process of ethical review.

It requires that the "four R" principles of *replacement, reduction, refinement and responsibility* be adhered to in the planning and conducting of animal studies. These values uphold the principles and practice of using the most humane methods on the smallest number of animals that will permit valid scientific information to be acquired.

It accepts that the use of animals in science critically depends on maintaining public confidence in the mechanisms and processes used to ensure that animal experiments are justified and humane.

2. REGISTRATION AND ACCOUNTABILITY

2.1 The SAMRC Ethics Committee for Research on Animals (ECRA) was established through a mandate of the National Health Research Ethics Council in keeping with the National Health Act (2003), section 73(1), which states that every organisation/institution, health agency and health establishment at which research using animals is conducted, must establish or have access to a registered Animal Research Ethics Committee (AREC).

2.2 As a committee established by the SAMRC Board in accordance with the South African Medical Research Council Act (Act No. 58 of 1991) and the SAMRC Research Ethics Policy (REP), the SAMRC ECRA is accountable to the SAMRC Board via its Research and Development Committee.
2.3 The SAMRC ECRA is registered with the National Health Research Ethics Council (NHREC; Registration number: AREC-190312-0011 valid until 31 December 2026).
2.4 These Terms of Reference should be read in conjunction with the SAMRC ECRA Standard Operating Procedures, the SAMR REP and the SAMRC Guidelines on the Responsible Conduct of Research.

3. MANDATE

3.1 The safety and efficiency testing of vaccines, medicine, medical appliances and materials, agricultural remedies, nutritional supplements, pesticides and other consumer products is mandated by various Statutes in South African Law. These laws are intended to promote the concept of preventative medicine which requires such substances to be tested for safety and efficiency before they may be approved and registered for public use.
3.2 This mandate for animal studies is, however, not absolute since progress is constantly being made in the development of methods for replacing animals in the safety testing of consumer products and medicines.
3.3 Any proposed use of animals for product safety testing must be preceded by a rigorous search for a validated animal replacement method. If such a method does not exist, then the proposed use must be supported by a specific statement explaining why an animal experiment is necessary.
3.4 The SAMRC Board requires that an ethical review process be established and maintained both within the SAMRC and at every institution where SAMRC-supported animal studies are undertaken.
3.5 The performance of this institutional ethical review process is a precondition of SAMRC support, collaboration and co-operation.

4. MEMBERSHIP

4.1 The SAMRC ECRA consists of members who collectively have the qualifications, expertise and experience to review and evaluate the science and ethics of the proposed research. The ECRA is multi-disciplinary and multi-sectorial in composition, with relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community.
4.2 The composition of the ECRA must adhere to the SAMRC REP and include members from the following categories:
- A veterinarian (Category A);
- Scientists with substantial and recent experience in the use of experimental animals (Category B);
- A representative from an animal welfare organization (Category C); and
- Representatives not involved in animal experimentation (Category D).
- A biostatistician.
- A person with a qualification in Law.

4.3 The SAMRC Board appoints the members of the ECRA in consultation with the President of the SAMRC after a competitive recruitment process has been followed in terms of the REP. Members serve for a term of three (3) years in the first instance. The term can be extended at the discretion of the Board.
4.4 At least 50% of members of the ECRA should be external to the SAMRC.
4.5 The ECRA chairperson will be recommended and appointed by the SAMRC Board for a period of 3 years. The chairperson shall be appointed in addition to categories A to D members.
4.6 The ECRA, when duly constituted and quorate, will elect and appoint a deputy chairperson by majority vote.
4.7 Only external members of the ECRA will be remunerated in accordance with SAMRC policies.
4.8 The ECRA may seek the expertise of external individuals and SAMRC researchers with specialised knowledge as required.

5. DUTIES AND RESPONSIBILITIES

5.1 The ECRA functions within the ambit of the SAMRC Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (2004) and the South African Bureau of Standards' South African National Standard (SANS 10386:2021) for the Care and Use of Animals for Scientific Purposes.
5.2 The ECRA will be responsible for *inter alia*, at least the following:
- Reviewing research proposals involving animals conducted by the SAMRC intra-mural units with consideration of the likely harm that may be caused to the animals and likely benefits that may arise from such work;
- Ensuring that animals involved in research are treated with respect and dignity and that their well-being is not compromised;
- Ensuring that the research is done according to high scientific, regulatory and ethics standards; and
- Granting approval where research proposals meet ethics standards and regulatory requirements.

5.3 The ECRA will have a secretariat with ethics training who will be responsible for *inter alia*, at least the following:
- Receipt of protocols after reviewing by the Scientific Review Committee;
- Compiling meeting agendas; and
- Administrative duties such as preparing minutes of meetings, record keeping, correspondence, handling queries, approving minor administrative amendments, managing all documentation related to the research studies, and updating the website.

5.4 The ECRA must direct researchers to report immediately anything that might warrant reconsideration of ethical approval of the protocol, including but not limited to the following:
- Serious or unexpected adverse effects on animals;
- Proposed changes in the protocol;
- Unforeseen events that might affect continued ethical acceptability of the project; and
- Termination or suspension of the project before the anticipated date of completion.

5.5 All matters reported to the secretariat regarding ECRA submissions are communicated to the chairperson as required and to all ECRA members when indicated. This includes operational issues at research sites that impact on research and animal well-being and/or safety.
5.6 The ECRA will evaluate applications for ethics approval in terms of its Standard Operating Procedures (as amended from time to time).
5.7 The ECRA should conduct a monitoring process on all research that is has approved either by submission of bi-annual and ongoing reports by the principal investigator (PI) or by any other appropriate form/activities. SAMRC ECRA should inform the PI in writing should concerns arise from the monitoring process.
5.8 The ECRA is encouraged to play an educative and supportive role by constructively engaging with researchers in order to improve their protocols, where concerns are highlighted, and to provide ethical advice as and when required by the researchers.
5.9 The code of conduct for the ECRA members is outlined in section 16 of the SAMRC REP.
5.10 All institutional animal ethics queries fall within the mandate of the ECRA and the SAMRC Research Integrity Office (RIO).
5.11 All matters of research integrity, including research misconduct, fall within the mandate of the SAMRC RIO.

6. CONFLICT OF INTEREST

6.1 ECRA members may have no undisclosed conflict of interest of any kind and must disclose actual, apparent or potential conflicts of interest to the committee. Conflicts of interest include direct benefits, such as research funding, or indirect benefits, such as the provision of material or facilities, or the support of individuals, including the provision of travel or accommodation expenses to attend conferences.
6.2 Members are required to sign a *conflict of interest agreement*. Any member of the ECRA who declares a conflict of interest with the submitted protocol, must recuse him/herself from the meeting when discussion and decision-making occurs on the protocol in which the member is directly involved as an investigator. Members may not use their membership to elicit an advantage.
6.3 A declaration of interest by all members will be completed at each meeting and managed accordingly. A member who is directly involved in a study conducted by an intramural unit will not be part of the decision-making on that study. When a study from a member's unit is discussed, he/she may provide information for clarification but will not participate in decision-making if he/she is directly involved. Offering clarification will not necessarily give that application an unfair advantage as any researcher may be invited to meetings to provide clarification. Clarification will be managed in an open and transparent manner.

7. CONFIDENTIALITY

7.1 All matters pertaining to the documents reviewed will be dealt with as confidential by all members of the ECRA and will not be distributed to a third party, unless required by law.
7.2 All members will sign a confidentiality agreement regarding meeting deliberations, applications, and information on research and related matters.

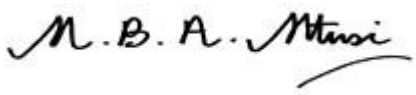
8. GENERAL

8.1 The SAMRC and its ECRA members must ensure that they receive initial and continued training in research ethics and science and are kept aware of current issues and developments in the broad area of research ethics and science.

8.2 The ECRA members are accorded indemnity by the SAMRC Board for legal action, e.g. liability consequent upon their decisions as ECRA members.

Level	3
Risk:	Strategic
Effective Date:	1 October 2025
Review Date:	September 2028
Policy Owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
Board Approval:	

Confirmation of Approval



10 December 2025

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Prof Ntobeko Ntusi
President and CEO

Date