SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

RESEARCH ETHICS POLICY

HUMAN RESEARCH ETHICS COMMITTEE (HREC) & ETHICS COMMITTEE FOR RESEARCH ON ANIMALS (ECRA)

Table of Contents

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1. Introduction

1.1 The Mission of the SAMRC is: "To improve the nation's health and quality of life by conducting and funding relevant and responsive health research, development, innovation and research translation". The SAMRC's statement of values also indicates that research must be of high quality and conducted with scientific integrity.

1.2 South Africa is a Constitutional Democracy whose Constitution (Act 108 of 1996) promotes and protects human dignity, equality and the advancement of human rights.

1.3 The SAMRC entrenches the culture of promotion of human rights as a core value in health research and elevates the critical role of the regulatory, legal and ethical framework plays in the conduct of research.

1.4 The regulatory, legal and ethical processes underpin and form an integral part of every research project be it human or animal. These processes are vital for assuring the quality and standard of research, i.e. responsible scientific enquiry. Scientific integrity is achieved through training and support for research and by ensuring that research is conducted within an appropriate regulatory, legal and ethical framework.

2. Purpose

2.1 To respond to the obligation set out by the National Health Act to institutions, health agencies and health establishments for the establishment of an institutional research ethics committee.

2.2 To provide guidance for the establishment, governance, and functions of the SAMRC Human Research Ethics Committee (HREC) as well as the responsibilities of the Ethics Committee for Research on Animals (ECRA).

2.3 To ensure that the SAMRC HREC and ECRA are constituted and functioning according to the Department of Health Guidelines, Ethics in Health Research: Principles, Processes and Structures, 2015.

2.4 To emphasize the importance of protecting human participants and animals in research where there are potential risks through due diligence (ethics review) before the research is initiated.

2.5 To ensure that SAMRC scientists respect the rights, dignity, safety, privacy and the health of research participants, humans and animals in all research activities.

2.6 To ensure that humans and animals are protected from harm (physical, psychological etc.) as a result of their involvement in research.

2.7 To implement and maintain the culture of research integrity and good research conduct for all science conducted by the SAMRC personnel and related external stakeholders.

3. Background

3.1 The National Health Act (NHA s72(1) mandates the Minister of Health to establish the National Health Research Ethics Council (NHREC). Section 72(6)(c) of the NHA gives authority to the NHREC to setting norms and standards for conducting research on humans and animals.

3.2 Protection of human participants in research is a shared responsibility between Principal Investigators (PIs), personnel involved in studies on human research, and the HREC or

ECRA. Research involving human participants can either be medical, clinical or non-clinical (social science)[1].

3.3 The SAMRC recognises the ethical dilemma posed by using sentient animals (i.e. animals that have sensations and experience emotions) for research, teaching and testing. It subscribes to the ethics of supporting studies which promise to contribute to the understanding of biology and environmental principles and to the acquisition of knowledge that can reasonably be expected to benefit humans, animals or the environment[2] .

3.4 The SAMRC acknowledges 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. The SAMRC 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.

3.5 It is against this background that the NHA mandates that every institution, health agency and health establishment at which health research is conducted must establish or have access to a research ethics committee (REC) for research involving human participants and research using animals registered with and accredited by the NHREC.

3.6 Most research requires ethics review, however, the Guidelines: Ethics in Health Research: Principles, Processes and Structures- 2015, clauses 1.1.8 to 1.1.11 states the following:

3.6.1 Research that relies exclusively on publicly available information or accessible through legislation or regulation usually need not undergo formal ethics review. This does not mean that ethical considerations are irrelevant to the research.

3.6.2 Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review, provided that:

(a) the researcher does not interact directly with individuals or groups
(b) the researcher does not stage any intervention
(c) the individuals or groups do not have a reasonable expectation of privacy
(d) dissemination of research findings does not identify individuals or groups

3.6.3 Research that relies exclusively on secondary use of anonymous information or anonymous human biological materials usually need not undergo formal ethics review, provided that no identifiable information is generated.

3.6.4 Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews usually do not constitute research and thus usually do not undergo formal ethics review. It should be noted, however, that if publication of such studies is desirable, it is prudent to obtain ethics approval before the study begins.

4. Application

4.1 This policy applies to all SAMRC researchers, research ethics committees of the SAMRC, research ethics screening sub-committees of the SAMRC and researcher(s)/institution(s) conducting research within, and/or on behalf of, the SAMRC.

[1] . "Definition of Human Subject Research" Research Administration, University of California, Irvine. Accessed March 2, 2017
[2] Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (2004).

4.2 Policy is also applicable in case of researchers from other institutions who have requested SAMRC's HREC or ECRA review for their research due to the absence of another suitable HREC and ECRA.

5. Scope

5.1 Ethics review and approval by a registered research ethics committee is required for the following "health research"[3]:

5.1.1 Biomedical research.

5.1.2 Humanities, social and behavioural sciences research, except for research excluded in terms of the Guidelines: Ethics in Health Research: Principles, Processes and Structures-2015, clauses 1.1.8 to 1.1.11).

5.1.3 Research that involves use of human biological materials and data collected from living or deceased persons, including human embryos, fetuses, fetal tissue, reproductive materials, and stem cells.

5.1.4 Any other research that may raise ethical issues/concerns, cause political/social tensions or have impact on cultural values.

6. HREC and ECRA Roles

6.1 The SAMRC HREC and ECRA will function according to a comprehensive set of Guidelines, Frameworks, Policies and Procedures as outlined in this Research Ethics Policy (REP) without limitation.

6.2 SAMRC HREC and ECRA must protect the interests (rights and welfare) of the research participants who volunteer to take part in research that has been evaluated to be scientifically sound.

6.3 In the case of research involving humans, the HREC is responsible for deciding independently whether the proposed research protects the interests of participants adequately and keeps to exemplary standards in research activities, as per the SAMRC's guidelines on the responsible conduct of research.

6.4 In the case of research involving animals, the primary role of ECRA is to protect the welfare interests of animals used or to be used in research.

6.5 SAMRC HREC and ECRA are encouraged to play an educative and supportive role by constructively engaging with researchers in order to improve their protocols, where concerns are highlighted.

6.6 SAMRC HREC and ECRA should monitor progress of research for which approval is granted, starting from time of approval to the termination of research.

7. Established SAMRC RECs

7.1 Human Research Ethics Committee (HREC)

7.1.1 The SAMRC HREC is 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 health

[3] 'Health research' as per the National Health Act No 61 of 2003 includes any research that contributes to knowledge of: the biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances, and the development of applications of health technology.

and health-related research involving human participants is conducted, must establish or have access to a registered HREC.

7.1.2 It shall function within the ambit of the National Health Act, 2003 (Act 61 of 2003); the Department of Health Guidelines, Ethics in Health research: Principles, Structures and Processes, 2015; the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition, 2006, as well as ICH GCP guidelines, E6(R2) 2016, CIOMS guidelines, 2016 and the Declaration of Helsinki, 2013.

7.1.3 It shall provide competent and timely prospective ethical review for research proposals involving humans (health research) conducted by the SAMRC Intra-Mural Units.

7.1.4 In the case of multi-centered clinical trials or other research, where other NHREC registered institution HRECs are reviewing the same protocol, the SAMRC HREC may as per the spirit of reciprocity, accept the approval granted by an NHREC-registered third-party HREC.

7.1.5 Similarly, the SAMRC HREC may also evaluate non-SAMRC affiliated research or be the lead HREC to review a multi-centered clinical trial or other research project, although, such applications may be subject to a fee payable to the SAMRC.

7.1.6 The SAMRC HREC's objective in reviewing research involving human research participants is to contribute to safeguarding the dignity, rights, safety and well-being of all research participants and to ensure that the goals of research do not override the best interests of the research participants.

7.1.7 The SAMRC HREC will grant approval where research proposals meet ethical standards and regulatory requirements

7.1.8 Some Proposals may receive triage from an ad-hoc HREC subcommittee, consisting of the HREC Chairperson and other two members of the SAMRC-HREC (subject experts/ethicists) who will determine whether research proposals require full or expedited ethics review or are eligible for a waiver.

7.2 Ethics Committee for Research on Animals (ECRA)

7.2.1 The SAMRC ECRA is 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 health research using animals is conducted, must establish or have access to a registered Animal Research Ethics Committee.

7.2.2 It shall function within the ambit of the South African Medical Research Council (SAMRC) Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (2004); The South African Bureau of Standards' South African National Standard (SANS 10386:2008 or latest version) for the Care and Use of Animals for Scientific Purposes.

7.2.3 It shall provide competent and timely prospective ethical review for research proposals involving animals conducted by the SAMRC Intra-Mural Research Units. ECRA may consider approval granted by an NHREC-registered third-party ECRA, where a reciprocal recognition agreement is in place.

7.2.4 May evaluate non-SAMRC affiliated research involving animals at the discretion of the chairperson of the committee; however, such applications may be subject to a fee payable to the SAMRC.

7.2.5 Its objective in reviewing research involving animals is to examine research proposals with reference to the likely harm that may be caused to the animals and likely benefits that may arise from such work and to determine how these considerations are weighted in relation to each other.

7.2.6 It will grant approval where research proposals meet ethics standards and regulatory requirements.

8. HREC and ECRA Membership

8.1 HREC Membership

8.1.1 Shall be multi-disciplinary, multi-sectoral, diverse and will broadly reflect the demographic profile of the South African population.

8.1.2 Shall cater for both genders, although not more than 70 % should be either male or female.

8.1.3 Shall have at least nine (9) and no more than twelve (12) members.

8.1.4 Shall have at least 50% members of the committee who are not employees of the SAMRC.

8.1.5 Fifty (50%) plus one member constitute a quorum.

8.1.6 HREC voting membership shall consist of the following:

(a) at least one member with knowledge of, and current research experience in, the professional care, counselling or health-related treatment of people. Such a member might be e.g. a medical practitioner, psychologist, social worker or nurse

(b) at least one member with professional training and research experience in qualitative research methodologies.

(c) at least one member with professional training and research experience in quantitative research methodologies.

(d) at least one member with experience of research involving collection of human tissues.

(e) at least one member with knowledge of, and current experience in areas of research that are likely to be regularly considered by the HREC.

(f) a member with expertise in biostatistics.

(g) a member with expertise/experience in clinical trial research, as evidenced by being a current Investigator of Record or Protocol Chair of a Clinical Trial.

(h) at least one member who is legally qualified, and who has an understanding of medical research.

(i) at least two layperson persons who have no affiliation to the SAMRC, are not currently involved in medical, scientific or legal work and are preferably from the community, or represent communities where research is conducted or is to take place.

(j) at least one person with a disability.

8.1.7 HREC members may represent more than one of the above skill categories or categories of personal attributes.

8.1.8 Research Integrity Officer or his/her representative, and the secretariat supporting the functions of the HREC will be non-voting member of the HREC, and will maintain confidentiality similar to the voting HREC members.

8.2 ECRA Membership

8.2.1 Shall have at least six (6) but no more than nine (9) members.

8.2.2 Shall have at least 50% members of the committee should be external to the SAMRC.

8.2.3 Fifty (50%) plus one member present at the meeting shall constitute a quorum.

8.2.4 ECRA membership shall consist of the following disciplines:

(a) At least one veterinarian.

(b) At least two scientists with substantial and recent experience in the use of experimental animals.

(c) At least one representative from animal welfare organization.

(d) Representatives not involved in animal experimentation.

8.3 **Resignation and Termination**

8.3.1 HREC or ECRA member who can no longer serve on the committee may resign. Resignation must be submitted in writing and there is no need to disclose reasons.

8.3.2 Should HREC or ECRA member fail to comply with contents of this REP on matters relating to HREC or ECRA members or discloses an unmanageable conflict of interest he/she will be requested to resign by the SAMRC Board on written recommendation by the President/Executive Management Committee and R&D Committee.

8.3.3 If a member fails to resign after directed to do so, SAMRC Board is entitled to terminate the member's appointment based on the reasons provided in the recommendation referred to in 8.3.2.

8.3.4 A vacancy should be filled timeously with a person of the same skill set.

9. Scientific review

9.1 Research proposals must pass scientific review before submission to the HREC or ECRA for ethical review in order to ensure that sound and valid scientific methods are applied to the study.

9.2 In the case of the HREC, scientific review will be managed and quality assured by the Executive Scientist, and in the case of the ECRA this will be done by a scientific review committee. Both processes will operate according to their respective Standard Operating Procedures (SOP).

9.3 Below is a summarized description of the scientific review process:

Stage	Research involving humans	Research involving animals	Notes
1	Unit/Platform Director or designee, will review and approve proposal for submission to the next stage	Unit/Platform Director or designee, will review and approve proposal for submission to the next stage	Rejected proposals must not be submitted for the next stage
2	Submission to the office of the Executive Scientist for initial screening for completeness	Not applicable	Incomplete proposals will be returned to the Principal Investigator (PI), copying Unit Director (where applicable)
3	Scientific review and quality assurance by the Executive Scientist.	Not applicable	Proposals with obvious problems will be returned to the PI prior to the independent review, copying Unit/Platform Director (where applicable)

4	Independent scientific review by appropriate scientific reviewers appointed by the office Executive Scientist.	Submission of proposal for review by the formalized scientific review committee.	PI must respond to comments to the satisfaction of the reviewers. NB: In case of the research involving humans, the Executive responsible for Research Strategy will determine if proposal requires further revision or is quality assured for the HREC.

9.4 A copy of the scientific review form containing the reviewers' comments, response thereto by the researcher and the reviewers' approval will be part of the documents submitted to the HREC or ECRA. This will streamline the process and allow the HREC and ECRA to focus on the ethics issues, knowing that an in-depth scientific review has been performed and the protocol stands up to the scientific scrutiny appropriate to the discipline concerned.

9.5 Notwithstanding reviews referred to in this section 9 of this policy and keeping in line with section 1.6.4 of the Guidelines: Ethics in Health Research: Principles, Processes and Structures-2015, HREC or ECRA may initiate additional scientific review where required.

10. Application for ethics review

10.1 Refer to the respective HREC (Human) and ECRA (Animal) SOPs'.

11. Ethics review

11.1 The SAMRC is committed to promoting ethical conduct of research which entails co-operation between HREC or ECRA and researchers to ensure a comprehensive and frank assessment of the ethical implications of proposals so that participants (and researchers) can be protected appropriately.[4]

11.2 SAMRC HREC or ECRA must review research proposals prospectively to ensure that they meet the accepted ethical norms and standards before research commences. In the case of research pertaining to existing data, expedited review may be considered.

11.3 Ethics review shall be in terms of the Guidelines: Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2015 and most updated versions of the REP and Research Ethics Standard Operating Procedures.

11.4 SAMRC HREC and ECRA members are encouraged to be objective, informed and to act without fear or favour in their ethical reviews.

11.5 SAMRC HREC and ECRA must also assess how the research will be conducted, whether the investigators are suitably qualified, that adequate monitoring and safety measures are in place and achievable, and the site is suitably resourced.

11.6 HREC and ECRA shall make provision for the full, expedited and waived ethical review processes.

[4] Wassenaar, D. 2006**.** Ethical issues in social science research. In Terre Blanche, M. Durrheim, K. and Painter, D. (eds) Research in practice: allied methods for the social sciences, 60–79. Cape Town: University of Cape Town Press.

11.7 Applicants shall stipulate data management plan (DMP) in their protocols. The DMP will include but not limited to data collection, storage, security, compliance to legal requirements, adherence to ethical requirements, sharing and access.

11.7.1 Research that poses no more that minimal risk of harm will be handled through expedited review process.

11.8 Waiver for ethical review will be granted as per the NDOH Ethics in Health Research: Principles, Processes and Structures, 2015, clauses 1.1.8 to 1.1.11.

11.9 In the case of research involving humans, the HREC should ensure that proposals submitted for review follow the broad ethical principles of:

11.9.1 Beneficence and non-maleficence: Maximizing benefit and minimizing harm.

11.9.2 Distributive justice (equality): Fair balance of risk and benefits amongst all role players involved in research.

11.9.3 Respect for persons (dignity, autonomy and informed consent): Treat people with respect and permit them to exercise self-determination.

11.10 In the case of research involving animals, ECRA should ensure that proposals submitted for review follow the following ethical principles of:

11.10.1 Reduction: reduce number of animals in experiments by designing strategies that facilitate use of the smallest numbers that will allow valid information to be obtained from the study.

11.10.2 Refinement: refine animal sourcing, care practices and experimental procedures to minimize or remove physical and psychological distress, within the limitations imposed by the requirements of the research.

11.10.3 Replacement: Replace sentient animals with non-sentient research models or systems in order to eliminate the use of animals that can experience unpleasant sensations.

11.11 HREC may not review, approve or provide clearance retrospectively in the case of prospective research.

11.12 Should applicant not respond to comments/queries raised by the HREC/ECRA within a period of 6 months after the latest feedback, such application may lapse at the discretion of HREC/ECRA. If lapsed, fresh application should be submitted.

12. Recognition of third party HREC or ECRA

12.1.1 SAMRC may recognise a third-party HREC/ECRA, provided it is registered with the NHREC.

12.1.2 The SAMRC may accept prior review and approval provided by the third-party HREC or ECRA, subject to the principal investigator submitting documents required by the SAMRC HREC or ECRA, which at minimum, must include the approved version of the proposal and all supporting documents submitted to the HREC or ECRA and a copy of the approval letter from the third-party HREC or ECRA.

12.1.3 This reciprocal recognition does not give researchers liberty to bypass submission of research proposal to the SAMRC HREC or ECRA. Therefore, research proposal documentation must be submitted to the SAMRC HREC or ECRA in the first instance. However, when recognition of third party approval is sought, investigators do not need to submit their documentation to the SAMRC HREC or ECRA in the normal format required by the SAMRC but should rather submit the proposal in the format that was approved by the third-party HREC or ECRA.

13. Jurisdiction outside the Republic of South Africa

13.1 SAMRC researchers conducting research outside the borders of the Republic of South Africa must get HREC or ECRA approval for the research from the country in which data will be collected as well as from the HREC or ECRA of the SAMRC, unless there is no suitable HREC or ECRA that can give this.

13.2 Where approval for research in another country has been given by an appropriate local HREC or ECRA, SAMRC researchers must submit the approved version of the proposal and all attachments and the letter of approval to the SAMRC HREC or ECRA. The proposal must pass Scientific Review and the SAMRC HREC or ECRA may request additional information if the level of detail required by the approving ethics committee in the other country is insufficient to meet South African standards of ethical review.

13.3 SAMRC HREC or ECRA will defer to the other committee on matters related to cultural issues, budget, approvals for research site access and any specific requirements of consent forms.

13.4 For multi-country studies, the HREC or ECRA will allow research to commence in sites after the national HREC or ECRA has given approval. This may be before all approvals have been received from all sites.

14. REC members' appointment and assurance

14.1 In keeping with the SAMRC Act (1991) s8 and s17, SAMRC Board delegates processes leading to appointment of HREC or ECRA members to the SAMRC President.

14.2 A call will be advertised for HREC or ECRA members and they will be appointed from among the nominated individuals, and if necessary by co-option.

14.3 SAMRC Board will review recommended names of potential HREC or ECRA members in consultation with the SAMRC President and shall make the final appointment of the HREC or ECRA members, including the Chairperson.

14.4 HREC and ECRA members will be appointed for a 3-year term and some member's appointments may be renewed for continuity purposes at the discretion of the Board, in consultation with the SAMRC President. The term can be renewed twice, after which the person should have a cooling-off period of at least one term.

14.5 HREC or ECRA chairperson may transition from being an ordinary member, but in her or his capacity as Chair the term can only be renewed once

14.6 During their term of office, HREC and ECRA members will be indemnified from personal liability against claims that may arise during ordinary business of the SAMRC HREC or ECRA, provided that members act in good faith.

15. Remuneration and reimbursement for the HREC or ECRA members

15.1 Only HREC and ECRA members external to the SAMRC shall be eligible for remuneration.

15.2 Eligible members will be remunerated in line with the National Treasury Instruction on Remunerations Levels: Service Benefit Packages for Office-Bearer of Certain Statutory and Other Institutions (as amended), at Sub-category C2 level.

15.3 Though the position of Deputy Chairperson is recognized; however, the Deputy Chairperson, if an external appointee will be remunerated as an ordinary member since he/she will only act as Chairperson in the absence of the Chairperson. The Deputy

Chairperson is not encumbered with additional functions above that of an ordinary member.

15.4 Remuneration for eligible members will be based on one day preparation time and meeting attendance. Remuneration for ad hoc meetings will be based on the number of hours of the meeting. Remuneration for preparation time will be as required.

15.5 For cost containment purposes, SAMRC may implement remuneration of HREC and ECRA members at levels lower that National Treasury's Instruction Note.

15.6 Eligible HREC or ECRA member who has resigned or his/her appointment terminated will not be remunerated for the remaining part his/her appointment period.

15.7 Reimbursements shall be in line with the SAMRC Subsistence and Travel Policy and Standard Operating Procedures.

16. Code of Conduct for the HREC and ECRA members

16.1 Meeting Attendance and Round Robin Process

16.1.1 HREC and ECRA will have about ten (10) and four (4) meetings a year respectively.

16.1.2 In the case where there are no issues to discuss and/or submissions to review, HREC or ECRA members will be notified in time regarding cancellation of a scheduled meeting.

16.1.3 HREC and ECRA Secretariat will publish closing dates for protocol submissions, and the meetings dates on the SAMRC webpage: http://www.mrc.ac.za/ethics/ethics.htm

16.1.4 Accepting appointment to the SAMRC HREC or ECRA indicates the in-principle commitment to attend scheduled/ad-hoc/emergency meetings and to participate in round robin processes.

16.1.5 Emergency and urgent decisions may be taken through ad hoc/special meetings or round robin process, provided there is a quorum (see section 8.1.5). Decision taken will be equivalent to the decision of the committee and must be recorded in the minutes of the next meeting.

16.1.6 HREC or ECRA member who is absent for two consecutive scheduled meetings, without submitting apology or explanation, may be relieved of his/her duties.

16.1.7 HREC or ECRA members' apologies and explanations for absence from the meeting must be submitted in writing to the Secretariat preferably before the meeting.

16.1.8 HREC or ECRA members who are unable to attend meeting may submit their views in writing.

16.2 Diligent Performance

16.2.1 Actively participate in the deliberations.

16.2.2 Exercise due diligence, appropriately apply their minds to the ethical issues of research design and conduct, raise pertinent concerns and make specific requests for changes to submissions where these are required and observe high standards of accuracy of response(s) provided and adhere to the timeliness.

16.2.3 Follow a professional and ethical approach to service at all times.

16.2.4 Where necessary actively engage with researchers, where there are issues with research proposals or conduct, to ensure that the problems are resolved timeously and research is subject only to minimal necessary delays.

16.2.5 Personal opinions must not cloud judgement.

16.3 **Respect, Honesty, Transparency and Fairness and Equity**

16.3.1 Integrity, honesty, highest ethical standards and appropriate behavior must be observed at all times.

16.3.2 Treat all stakeholders with respect and aim to work in a transparent, fair and equitable manner.

16.4 **Conflict of Interest**

16.4.1 HREC and ECRA members may not have 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.

16.4.2 Members are required to sign a conflict of interest agreement. Any member of the Committee who presents 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.

16.4.3 A declaration of interest by all members will be completed at each meeting and managed accordingly. No member will be part of decision-making on any study in which they are directly involved. When a study from a member's Unit/Platform is discussed, they may give information for clarification but shall not participate in decision making if they are directly involved. Giving clarification will not necessarily give that application an unfair advantage as any researcher may attend meetings to provide clarification. Clarification will be managed in an open and transparent manner.

16.5 **Confidentiality**

16.5.1 All matters pertaining to the documents reviewed will be dealt with as confidential by all REC members and will not be shared with a third party, unless required by law.

16.5.2 All members will sign a confidentiality agreement regarding meeting deliberations, applications, and information on research and related matters.

16.6 **Independence, Impartiality and Objectivity**

16.6.1 All members of HREC and ECRA have responsibility to independently, impartially and objectively review proposed research and determine whether it is likely to be conducted in a manner that will protect participants from harm (in case of the HREC) and, protect safety and welfare of animals used in research (in case of ECRA).

16.7 **Suspension or discontinuation of projects**

16.7.1 HREC or ECRA can only suspend or withdraw approval after a due, fair and transparent process has been followed, including but not limited to the engagement with the Principal Investigator, Executives responsible for Research Operations and Compliance, and Research Strategy (only related to HREC).

16.7.2 Suspension should be a course of action only if it is determined that continuation of research will likely result in harm to research participants and remedial measures to protect participants cannot be instituted without research project suspension. Alternatively, suspension may be instituted where reasonable remedial measures have

been proposed by the REC and supported by the Executives responsible for Research Operations and Compliance and Research Strategy (only related to HREC) and the Principal Investigator does not implement them within stipulated timelines.

16.7.3 Withdrawal of approval should be a course of action when it is determined that the risk of harm to participants in research is real and substantial, and where there are no prospects of remedial measures reducing or removing the threat.

16.7.4 REC may suspend the study if it is not being conducted in accordance with the approved protocol.

16.8 **Complaints**

16.8.1 As a starting point, complaints about HREC or ECRA -related business/decision(s) must be submitted to the HREC or ECRA secretariat for attention of the HREC or ECRA in the first instance.

16.8.2 In the event that the complaints remain unresolved at HREC or ECRA level, they should be escalated to the Executive responsible for Research Operations and Compliance. In this instance, attempts will be made to resolve the matter through mediation with the HREC or ECRA members.

16.8.3 Should mediation fail, complaints will be referred to the SAMRC R&D Committee of the Board for intervention.

16.8.4 In the event that the matter remains unresolved at the SAMRC R&D Committee level, complaint shall be reported to the NHREC for adjudication.

16.9 **Appeals**

16.9.1 As a starting point, appeal(s) against HREC or ECRA -related business/decision(s) must be submitted to the HREC or ECRA secretariat for attention of the HREC or ECRA in the first instance.

16.9.2 Appeal(s) must contain clear reasons, motivation and desired results.

16.9.3 HREC or ECRA should resolve the matter expediently, preferably within seven (7) business days after receipt of such submission.

16.9.4 In the event that the matter is not satisfactorily resolved at the HREC or ECRA level, PI may escalate the matter to the Executives responsible for Research Operations and Compliance and Research Strategy. The Executives, after consultation with the SAMRC President, will set up an independent expert committee to review matter. The expert committee's recommendation will be final and binding to all parties.

16.10 **Training**

16.10.1 The SAMRC HREC and ECRA members, and researchers must ensure that they receive initial and continued education/training in research ethics and are kept aware of current issues and developments in the broad area of research ethics and science.

16.10.2 It is expected for SAMRC HREC/ECRA and researchers to attend applied ethics training every two years.

16.10.3 It is a requirement that some HREC members, researchers and co-workers have GCP training evidenced by a certificate not older than 3 years.

16.10.4 The SAMRC- Research Integrity Office will cover the above training costs for the HREC and ECRA members.

16.10.5 The SAMRC Units/Divisions will be responsible for their staff training costs.

17. Consultants/External Experts

17.1 Where deemed necessary, consultants might from time-to-time be engaged to assist HREC or ECRA with the reviews of research proposals. This will normally be due to proposals requiring very special expertise for ethics review that is not available among HREC or ECRA members.

17.2 Alternatively, consultants may be engaged if the HREC or ECRA members with expertise in a complex area all declare conflict of interest on a proposal.

17.3 Consultants shall observe confidentiality and declare their interests similar to the HREC or ECRA members as outlined above.

17.4 Engagement with consultants will be permitted with prior discussion with- and approval by the Executive Responsible for Research Operations and Compliance.

17.5 Request to engage consultants shall not be unreasonably rejected.

17.6 As an alternative to the use of consultants, the HREC or ECRA may request special training in emerging thematic areas or methods of importance to matters being placed before the committee. Where resources are required for this it should be arranged with approval from the Executive responsible for Research Operations and Compliance.

18. Administrative/Secretarial Support

18.1 REC's administrative and secretarial support will reside within the SAMRC Ethics office with reporting line to the Research Integrity Officer (RIO)

18.2 Secretariat shall be responsible for among others, the following**:**

18.2.1 Receipt of protocols.

18.2.2 Preliminary protocol screening.

18.2.3 Liaising with the Office of the Executive responsible for Research Strategy for scientific review of protocols.

18.2.4 Administrative duties, including but not limited to, compiling meeting agenda, preparing minutes of meetings, record keeping, correspondence, handling queries, managing all documentation related to the research studies, and updating the website.

18.2.5 Travel arrangements and processing claims.

19. Misconduct

19.1 All research carried out under the auspices of the SAMRC shall comply with the provisions of this policy and its standard operating procedures (SOP), and related policies, procedures and guidelines.

19.2 Any research study or researcher that is suspected to be in breach of this policy and / or its SOP and related policies, procedures and guidelines must be reported to the Research Integrity Office (RIO) https://transgression.samrc.ac.za

19.3 RIO will setup enquiry(ies) for all reported allegations and recommend necessary actions (where required).

20. SAMRC Responsibility towards the HREC and ECRA

20.1 Provision of facilities, powers and resources to enable the REC to fulfil its mandate.

20.2 Provide funding for continued ethics, GCP, GLP etc. training for researchers and HREC and ECRA members, where applicable.

21. Researchers Responsibility towards the HREC and ECRA

21.1 Comply with this policy and is associated SOP and related policies, procedures and guidelines, all relevant legislation, statutory and non-statutory codes and official.

22. REC Registration

22.1 In line with NHA s71, HREC and ECRA must at all times have valid and active registration with NHREC.

22.2 In addition to registration with NHREC, SAMRC HREC may register with other relevant bodies such as the United States of America (USA) Office for Human Research Protections (OHRP), Federal-Wide Assurance and Institutional Review Board.

23. Reporting and Audit

23.1 SAMR HREC and ECRA must report annually to the NHREC on their activities on or before 28 February of each year.

23.2 SAMR HREC and ECRA should make relevant records available for inspection and audit by the NHREC (or its delegate) upon request.

23.3 SAMR HREC and ECRA must submit quarterly reports to the Executive responsible for Research Operations and Compliance for tabling at the Research and Development Sub-committee of the Board meeting.

24. Legislative and Regulatory Frameworks

24.1 **Legislation:**

24.1.1 Animal Health Act 7 of 2002.
24.1.2 Animal Protection Act 71 of 1962.
24.1.3 Animal Diseases Act (Act No 35 of 1984).
24.1.4 The National Parks Act (Act No 57 of 1976).
24.1.5 The Nature Conservation Ordinances of the provinces of South Africa.
24.1.6 Children's Act 38 of 2005.
24.1.7 Constitution of the Republic of South Africa Act 108 of 1996.
24.1.8 Hazardous Substances Act 15 of 1973.
24.1.9 Health Professions Act 56 of 1974.
24.1.10 Human Tissue Act, Act No 65 of 1983.
24.1.11 National Health Act, Act No 61 of 2003.
24.1.12 National Environmental Management Act 107 of 1998.
24.1.13 National Health Laboratory Service Act 37 of 2000.
24.1.14 Rules Relating to the Practicing of the Para-Veterinary Profession of Laboratory Animal Technologist. Department of Agriculture (1997) GN 1445 of 3 October 1997.
24.1.15 Societies for the Prevention of Cruelty to Animals Act 169 of 1993.
24.1.16 Veterinary and Para-Veterinary Professions Act 19 of 1982.

24.2 **Regulatory Frameworks/Guidelines:**

20.2.1. Ethics in Health Research: Principles, Processes and Structures, Department of Health (2015). http://nhrec.health.gov.za/index.php/grids-preview

20.2.2. Guidelines on Ethics for Medical Research. Books 1-5, SAMRC. http://www.mrc.ac.za/research/ethics/guideline-documents

20.2.3. Guidelines on Ethics for Medical Research: Use of Animals in Research and Training (Book 3), South African Medical Research Council (2004).

20.2.4. Guidelines on Ethics for Medical Research: Use of Biohazards and Radiation (Book 4), South African Medical Research Council (2002).

20.2.5. Guidelines on Ethics for Medical Research: General Principles (Book 1), South African Medical Research Council (2000).

20.2.6. Ethics in Health Research: Principles, Processes and Structures, Department of Health (2015). Accessible at: http://www.doh.gov.za/search/index.html.

20.2.7. The South African Medical Research Council Guidelines on the Responsible Conduct of Research (2017).

20.2.8. South African Good Clinical Practice for Clinical Trials. Department of Health (2006). Accessible at: http://www.kznhealth.gov.za/research/guideline2.pdf

24.3 **International Treaties and Conventions:**

24.3.1 Belmont Report 1979. Accessible at: http://www.hhs.gov/ohrp/policy/belmont.html.

24.3.2 CIOMS 2016. International Ethical Guidelines for Health-related Involving Humans. Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Accessible at: http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf.

24.3.3 Declaration of Helsinki, 2013. Accessible at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

24.3.4 The Convention on International Trade in Endangered Species (CITES).

25. Related Policies, Procedures and Guidelines

25.1.1 Subsistence and Travel Policy. https://samrc.sharepoint.com/:b:/r/finance/Policy%20Documents/SubsistenceTravelPolicy.pdf?csf=1&e=66wSi0

25.1.2 Subsistence and Travel Standard Operating Procedures. https://samrc.sharepoint.com/:b:/r/finance/Procedure%20documents/SubsistenceTravelSOP2.pdf?csf=1&e=kOWrEc

25.1.3 Supply Chain Management Policy. http://www.samrc.ac.za/sites/default/files/attachments/2016-06-14/SupplyChainManagement.pdf

25.1.4 Supply Chain Management Standard Operating Procedures. https://samrc.sharepoint.com/:b:/r/scm/Procedure%20documents/SupplyChain.pdf?csf=1&e=ZPAYZp

25.1.5 SAMRC Guidelines on the Responsible Conduct of Research. https://www.samrc.ac.za/sites/default/files/attachments/2018-06-27/ResponsibleConductResearchGuidelines.pdf

25.1.6 Code of Business Conduct Framework Policy.
https://samrc.sharepoint.com/:b:/r/hr/Policy%20Documents/CodeBusinessConductFramework.pdf?csf=1&e=wlUfkG

25.1.7 Disciplinary and Grievance Policy.
https://samrc.sharepoint.com/:b:/r/hr/Policy%20Documents/GrievanceDisplinaryCode.pdf?csf=1&e=LJBo01

25.1.8 Delegation of Authority Framework Policy.
https://samrc.sharepoint.com/:b:/r/hr/Policy%20Documents/GrievanceDisplinaryCode.pdf?csf=1&e=LJBo01

25.1.9 Fraud Prevention Policy.
https://samrc.sharepoint.com/:b:/r/risk/Policy%20Documents/FraudPreventionPolicy.pdf?csf=1&e=tTeIA2

25.1.10 Risk Management Policy.
https://samrc.sharepoint.com/:b:/r/risk/Policy%20Documents/RiskManPolicy.pdf?csf=1&e=315h0i

25.1.11 Collaborative Research Policy.
https://samrc.sharepoint.com/general/Policy%20Documents/CollaborativeResearchPolicy.pdf

25.1.12 Safety, Health and Environment Policy.
http://www.samrc.ac.za/sites/default/files/attachments/2016-06-13/SafetyHealthEnvironment.pdf

24 Policy authority

24.1 The Executive Management Committee (EMC) is responsible for the maintenance and review of this policy, and alert Research and Development Sub-committee of the Board about changes.

Category:	Level 1
Risk:	Strategic
Effective Date:	31 July 2020
Review Date:	August 2022
Policy Owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
Board Approval:	30 July 20

Confirmation of Approval

06 August 2020

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Prof Glenda Gray
President

Date