THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
HUMAN RESEARCH ETHICS COMMITTEE (HREC)
CHARTER AND TERMS OF REFERENCE

PREAMBLE

The South African Medical Research Council (SAMRC) was established in 1969 with a mandate to improve the health of the country's population, through research, development and technology transfer, so that people can enjoy a better quality of life. The vison of the SAMRC is ***"****building a healthy nation through research and innovation*" with a mission *"to improve the nation's health and quality of life through promoting and conducting relevant and responsive health research"*.

The SAMRC Human Research Ethics Committee (hereinafter referred to as the HREC/Committee) was established in terms of the SAMRC Research Ethics Policy (REP) with the primary purpose of reviewing and monitoring research in the intramural units of the SAMRC from an ethical perspective. This includes protecting participant rights in research, as well as promoting ethical values and research integrity within the SAMRC.

All research conducted by a Principal Investigator (PI) or Co-Principal Investigator (Co-PI) who is an SAMRC employee must be of the highest ethical standard and must be undertaken with prior written approval from the SAMRC HREC.

1. REGISTRATION AND ACCOUNTABILITY OF THE HREC

1.1 The National Health Act (Act 61 of 2003) established a National Health Research Ethics Council (NHREC) within the South African National Department of Health and 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) registered with the NHREC.

1.2 The NHREC's Working Group for Norms and Standards revised the first edition of the Guidelines issued in 2004, and produced second edition entitled "Ethics in Health Research: Principles, Processes and Structures-2015" (hereafter "Guidelines 2015").

1.3 The Guidelines 2015 provide minimum national benchmark of norms and standard for conducting responsible and ethical research. The Guidelines 2015 also sets the basis for the SAMRC HREC's registration with the NHREC, and thus cannot be overridden by other international body's requirements.

1.4 The SAMRC HREC is registered with the NHREC in South Africa with registration number REC-130312-011 and in the USA with the Office for Human Research Protections (OHRP) with Federalwide Assurance number FWA00002753 and Institutional Review Board number IRB00001569. The SAMRC HREC will report to the aforementioned regulatory bodies as and when required in terms of its respective policies.

1.5 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 REP, the SAMRC HREC is accountable to the SAMRC Board via its Research and Development (R&D) Committee. The Chairperson of the HREC must submit quarterly reports to the Executive responsible for Research Operations and Compliance for tabling at the R&D Sub-committee of the Board.

2. MANDATE

2.1. The SAMRC HREC functions as the official Human Research Ethics Committee of the SAMRC. The objective of the Committee 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.

2.2. The HREC is committed to ensuring high-quality scientific and ethical research by the SAMRC, thereby protecting the professional interests of the researchers as well.

2.3. The SAMRC HREC aims to provide independent, comprehensive and timely review of the ethics of proposed studies conducted by SAMRC intramural units.

2.4. SAMRC HREC members are encouraged to be objective, informed and to act without fear or favour in their ethical reviews, and must ensure that research proposals stand up to scientific and ethical scrutiny appropriate to the disciplines concerned. SAMRC REP, section 9, makes provision for streamlining of the scientific review, without completely taking this function away from the SAMRC HREC as provided for in section 1.6.4 of the Guidelines 2015.

3. MEMBERSHIP

3.1. The SAMRC HREC consists of members who collectively have the qualifications, expertise and experience to review and evaluate the science, health aspects and ethics of the proposed research. The Committee 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.

3.2 The composition of the Committee must be according to national guidelines, as set out by the Department of Health in *Ethics in health research: principles, processes and structures*, second edition, 2015 and the SAMRC Research Ethics Policy

3.3 The Board of the SAMRC appoints the members of the Committee 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.

3.4 At least 50% of members of the Committee should be external to the SAMRC.

3.5 Only external members of the Committee will be remunerated in accordance with SAMRC policies.

3.6 The Committee, when duly constituted and quorate will elect and appoint a Deputy Chairperson by majority vote.

3.7 The Committee may seek the expertise of external individuals and SAMRC researchers with specialised knowledge as required. Where legal queries are raised by Committee members, these will be referred to the Legal division of SAMRC via the legal representative on the Committee.

3.8 Independence of the Committee is guided by international norms. **The WHO Standard 4: independence of research ethics committees[1] states:**

"…to ensure independence of the REC's operations, in order to protect decision-making from influence by any individual or entity that sponsors, conducts, or hosts the research it reviews… and to ensure that the REC cannot be pressured to approve or disapprove particular protocols, the charter, by-laws, policies and/or procedural rules of the REC provide that:

1. *The REC's membership includes at least one person with no connection to the organisation that sponsors or conducts the research under review;*
2. *Researchers, sponsors, and funders may attend an REC meeting to answer questions about their research protocols and associated documents, but they are not present when the REC reaches decisions about their proposed research;*
3. *Senior decision-makers of the entity creating the REC, or of any organisation that sponsors or conducts the research reviewed by the REC (such as the director of an institution, or his or her agent), do not serve as members of the REC or its Chair;*
4. *The entity that establishes the REC ensures that REC members are protected from retaliation based on positions taken with respect to REC-related matters or review of research projects."*

4. DUTIES AND RESPONSIBILITIES

4.1 The SAMRC HREC functions within the ambit of the National Health Act, 2003 (Act 61 of 2003); the *Guidelines* 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.

4.2 The HREC will be responsible for *inter alia*, at least the following:

- 4.2.1 Reviewing all intramural research proposals where the PI or Co-PI is an SAMRC employee to ensure that research conducted will promote health, and/or prevent disease and/or disability, and/or cure disease;
- 4.2.2 Ensuring that humans involved in research are treated with respect and dignity and that their well-being is not compromised;
- 4.2.3 Ensuring that the research is done according to high scientific, regulatory and ethics standards; and
- 4.2.4 Granting approval where research proposals meet ethics standards and regulatory requirements.

4.3 The HREC will have a secretariat with ethics training who will be responsible for *inter alia*, at least the following:

- 4.3.1 Receipt of protocols;
- 4.3.2 Preliminary protocol screening;
- 4.3.3 Arranging for scientific review of protocols;
- 4.3.4 Compiling meeting agendas; and

[1] World Health Organization (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.

4.3.5 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.

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

4.5 All matters reported to the Secretariat regarding HREC submissions are communicated to the Chair as required and to the full Committee when indicated. This includes operational issues at research sites that impact on research and participant well-being and/or safety.

4.6 The SAMRC HREC will evaluate applications for ethics approval in terms of its Standard Operating Procedures (as amended from time to time).

4.7 SAMRC HREC should conduct monitoring process on all research that is has approved either by submission of annual and ongoing reports by the principal investigator (PI) or by any other appropriate form/activities. SAMRC HREC should inform PI in writing should concerns arise from the monitoring process.

4.8 SAMRC HREC 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 advise as and when required by the researchers,

4.9 The code of conduct for the HREC members is outlined in section 16 of the REP.

4.10 All institutional ethics queries fall within the mandate of the HREC and the Research Integrity Office.

4.11 All matters of research integrity, including research misconduct, fall within the mandate of the Research Integrity Office.

5. CONFLICT OF INTEREST

5.1 SAMRC HREC 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.

5.2 Members are required to sign a *conflict of interest agreement*. Any member of the Committee 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.

5.3 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

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.

5.4 Members who are SAMRC employees serve on the Committee in their capacity to protect research participants' rights.

6. CONFIDENTIALITY

6.1 All matters pertaining to the documents reviewed will be dealt with as confidential by all members of the Committee and will not be distributed to a third party, unless required by law.

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

7. GENERAL

7.1 The SAMRC and its HREC 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.

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

Level:	3
Risk:	Strategic
Effective Date:	1 February 2023
Review Date:	January 2026
Terms of Reference owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
EMC Approval	

Confirmation of Approval

26 January 2023

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Prof Glenda Gray
President & CEO

Date