

CONSTITUTION AND CODE OF CONDUCT OF THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

Adopted at Pretoria on the 11th day of November 2015 at a full meeting of the National Health Research Ethics Council 2013-2016 appointed in terms of the National Health Act (Act 61 of 2003)

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1. Purpose of this document

The Health Research Ethics Council (NHREC), established in terms of s 72(1) of the National Health Act (NHA), is a statutory national body mandated to ensure that health research is conducted in accordance with the highest ethical standards and international best practice as well as to exercise oversight of the composition, competencies and operations of Health Research Ethics Committees including Animal Ethics Committees (referred to collectively as RECs). The activities of the NHREC are regulated by Regulations issued in terms of s 90 (1)(s) of the NHA.¹

The purpose of this document is to explain membership composition, appointment and termination procedures, the expected conduct of members, principles for managing conflicts of interest, misconduct procedures, meeting procedures, as well as descriptions of the terms of reference of committees and working groups of the NHREC.

Although the NHA and the relevant regulations do not require the NHREC to have a Constitution and Code of Conduct, in line with the principles of good governance, the NHREC believes it is best practice to outline the terms of reference, the expectations of members including conduct expectations, management of conflicts of interest, disciplinary measures in the event of breaches and so on.

2. Terms of Reference of the NHREC

Section 72 of the NHA stipulates the terms of reference for the NHREC: the Council must

- 2.1 Determine guidelines for the functioning of health research ethics committees (RECs).
- 2.2 Register and audit health RECs.
- 2.3 Set norms and standards for conducting research on humans and animals and norms and standards for conducting clinical trials.
- 2.4 Adjudicate complaints about the functioning of health RECs and hear any complaint by a researcher who believes he or she has been unfairly discriminated against by a health REC.
- 2.5 Refer to the relevant statutory health professional council matters involving violation or potential violation of an ethical or professional rule by a health care provider
- 2.6 Institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards or guidelines set for the conducting of research in terms of this Act.
- 2.7 Advise the national department and provincial departments on any ethical issues concerning research.
- 2.8 Set up working groups/task teams/sub-committees to carry out its functions.

¹ Government Gazette 33574 23 September 2010.

3. Membership of the NHREC

- 3.1 The Minister of Health appoints fifteen persons, after consultation with the National Health Council, chosen from nominations invited by the Minister by notice in the Government Gazette, in accordance with Regulation 3. Membership is constituted as follows:
- Nine with extensive experience and knowledge in health research ethics
 - A layperson
 - A representative from the Department of Health
 - A person with extensive knowledge of the pharmaceutical industry
 - A person with extensive knowledge of the Medicines Control Council
 - A person with extensive knowledge of the ethics of human health-related research using animals
 - A person with extensive knowledge of relevant law.
- 3.2 The Minister appoints the Chairperson and Vice-Chairperson in accordance with Regulation 4.
- 3.3 Members are appointed for three years but may be reappointed for one (1) or further terms. Generally, after a person has served three consecutive terms, she or he should step down for at least one term. This practice promotes capacity building.
- 3.4 A member may resign or be requested to do so by the Minister for good cause on the written recommendation of the Chairperson.
- 3.5 When a member steps down or dies, the Minister must fill the vacancy by appointing a person for the unexpired portion of the term of office of the NHREC.
- 3.6 A member who fails to observe NHREC meeting attendance requirements (see section 6 below), who fails to carry out duties and allocated tasks as required by the Chairperson, or who discloses a significant conflict of interest that cannot be managed appropriately (see section 5 below), may be requested to resign from the NHREC.
- 3.7 If the member fails to resign, the Chairperson (or delegated person) should recommend to the Minister in writing that he or she should terminate the member's appointment on the basis of the reasons supplied with the recommendation.

4. Standard of Conduct Expected of members

Members must affirm this undertaking annually at the first meeting of the calendar year.

- 4.1 In carrying out their duties, members of NHREC must
- 4.1.1 uphold ethical standards by acting to foster public confidence in the NHREC's ability to act in the public interest and for long term public good, to ensure that the integrity of the NHREC is maintained, and to promote the NHREC's goals;
- 4.1.2 demonstrate integrity, honesty, good judgement and professionalism;

- 4.1.3 perform their official duties and arrange their private affairs in a manner that will bear the closest public scrutiny; this obligation is not necessarily fully discharged simply by acting within the law;
- 4.1.4 make decisions in the interest of NHREC, with a view to the public interest, and with regard to the merits of each case;
- 4.1.5 disclose fully any private or professional interests that could affect NHREC actions or that could present a potential conflict of interest and put ethical practice at risk (see section 5 below);
- 4.1.6 arrange their private affairs in a manner that will prevent real, potential or apparent conflicts of interest from arising; if such a conflict does arise between the private interests of an individual and the official duties and responsibilities of that individual, the conflict must be disclosed and resolved in favour of the interest of NHREC (see section 5 below).
- 4.2 Notwithstanding other personal, professional, business or scientific activities, NHREC members are obliged to act in the best interest of the NHREC; to make objective decisions that facilitate appropriate strategic investment of public resources in the pursuit of the goals and objectives of the NHREC.
- 4.3 Members must use NHREC property of any kind, directly or indirectly, only for officially approved NHREC activities.
- 4.4 Upon termination of their term of office, members must not act so as to cause a perception that he or she is taking improper advantage of the office held previously.

5. Conflict of Interest

- 5.1 A conflict of interest occurs when an individual has an interest that competes with the interests of the NHREC. The competing interest may be real, potential or perceived, direct or indirect. The competing interest may cause people to think that the individual or the organisation to which he or she is attached is in a position to benefit from the situation or that the NHREC is not able to achieve an outcome that would be in the best interest of the NHREC because of the competing interest.
- 5.2 General conflict disclosure: All activities that involve research, commercial or financial interests, whether real, potential or perceived, which may conflict with an interest of the NHREC or with the duties of an individual member, must be disclosed promptly to the NHREC or to the appropriate officer of the NHREC.
- 5.3 Undesirable conflicts are research, commercial or financial interests in any transaction or initiative that would conflict with carrying out the duties of a NHREC member, with furthering the best interest of the NHREC or with promoting the NHREC's objectives.
 - 5.3.1 These conflicts include but are not limited to interests in entities that fund research or have an interest in the outcome of NHREC activities, a research contract, grant, award, contribution, research project or research-related business venture;
 - 5.3.2 The following factors alone will not invalidate a relationship between the NHREC and a member (or an enterprise in which the member has an interest):

- (a) the member has an interest in the relationship; or
 - (b) the member with an interest in the contract, grant, award, contribution, research project or research-related business venture was present at the meeting at which a decision about the relationship was made.
- 5.4 Disclosure: Disclosure of a conflict of interest, whether real, potential or perceived, must take place as soon as the individual or other interested party becomes aware of it.
- 5.4.1 The existence of a conflict of interest does not automatically prevent a member from participating in NHREC business.
- 5.4.2 When a conflict to be disclosed is confidential or sensitive, and may cause prejudice through open disclosure, the matter may be disclosed in confidence to the Chairperson (or delegated nominee).
- 5.4.3 The Chairperson has discretion to decide that the matter is not confidential or sensitive or that the interests of the NHREC cannot be served without full and open disclosure. The Chairperson must inform the member of this decision and give the member an opportunity to make open disclosure. If the member declines to make such disclosure, this omission shall be considered a breach of the expected conduct code (see section 8 below).
- 5.4.4 When a disclosed interest is determined by the NHREC to be a problem for maintenance of integrity for decision making of the Council, the member with the conflict of interest must recuse him or herself from the decision making process.
- 5.4.5 Should the conflict of interest be of such a nature and degree that the member's continued participation in the work of the Council poses a significant threat to the integrity of the Council's work, the member may be asked to resign from the Council and the Chair should recommend accordingly to the Minister (see sections 3.7 & 3.8 above).
- 5.5 Gifts and Benefits: members must not solicit or accept transfer of economic benefit, other than incidental gifts, customary hospitality, or other benefits of nominal value from persons, groups or organizations having, or likely to have, dealings with NHREC unless the transfer is pursuant to an enforceable contract or property right of the Council member, which should have been disclosed. The recipient of incidental gifts, customary hospitality or other benefits of nominal value must disclose this at the next meeting of the NHREC.
- 5.6 Preferential Treatment: members must not step out of their official roles to assist private entities or persons in their dealings with the NHREC where this could result in preferential treatment for any person or organization. The existence of preferential treatment is a question of fact rather than perception only.
- 5.7 Commitments: Members must ensure that their actions, whether professional or private, do not commit the NHREC to liability, and that all commitments and actions on behalf of the NHREC are undertaken in accordance with the NHREC's policies, regulations and statutory capacity.

- 5.8 Undue influence: Members must not use their influence or position to secure employment, funding or other special treatment for themselves, family members or business associates.

6. Meetings of the NHREC

Upon appointment of a new NHREC, the first meeting of the Council must be held within 30 days of appointment.

- 6.1 Meetings are conducted in terms of Regulation 6.
- 6.2 The *full membership* of the NHREC must meet at least four (4) times a year, dates of which are determined at the last meeting of the preceding year.
- 6.3 A quorum consists of a simple majority (fifty per cent plus one).
- 6.4 Items for the agenda must be requested by the Secretariat 30 days before the date of each meeting.
- 6.5 The agenda closes 15 days before the meeting and is distributed electronically with any supporting documents 10 days before the meeting.
- 6.6 Urgent items may be added to the agenda via the Chairperson up to three days before a meeting. The member concerned is responsible for circulating any documentation to all members.
- 6.7 Decisions should be reached by consensus if possible. When a vote is required, a simple majority serves, with the Chairperson having a casting vote in addition to his/her deliberative vote, should the vote be tied.
- 6.8 Apologies and explanations for absence must be submitted in writing to the Secretariat preferably before the meeting. Note that accepting appointment to the NHREC indicates the in principle commitment to attending the scheduled meetings (see section 6.1)
- 6.9 Emergency decisions required between meetings may be taken by the EXCO, which must report the details of the matter, including the basis for urgency, to the full Council at its next meeting.
- 6.10 The full Council must formally ratify the decision of the EXCO made in terms of section 6.9.
- 6.11 All meetings must be minuted comprehensively, including a record of discussion and dissent, as appropriate.
- 6.12 Minutes must be distributed by the Secretariat to all members for comment no later than 30 days after the meeting.

7. Reporting

The NHREC reports to the Minister at least twice a year. The Minister may call an ad hoc meeting when necessary.

8. Misconduct

Misconduct constitutes a failure to comply with the Constitution and Code of Conduct of the NHREC, including but not limited to

- Misleading the NHREC or misrepresenting the NHREC
- Abuse of privileged information
- Fabrication or falsification of reports
- Failure to disclose a material conflict of interest
- Divulging confidential information to a third party without permission
- Failure to attend a minimum of two consecutive NHREC meetings per annum

Allegations of misconduct may be investigated properly by the CADC, which makes a recommendation to EXCO.

9. Committees & Working Groups

9.1 The Executive Committee (EXCO): comprises of the Chairperson, Deputy Chairperson, Chairpersons of Working Groups and the Secretariat.

9.1.1 Terms of Reference: The EXCO must

- 9.1.1.1 direct NHREC operations between scheduled meetings;
- 9.1.1.2 oversee the functioning of the working groups;
- 9.1.1.3 identify and co-opt specialists to working groups as necessary;
- 9.1.1.4 formulate a strategic plan for NHREC in consultation with all NHREC members;
- 9.1.1.5 formalise relationships with key role players, such as the National Health Research Committee, the Medicines Control Council (or its successor) and other professional bodies, by way of Memoranda of Agreement;
- 9.1.1.6 ensure the visibility of NHREC and highlight its activities amongst relevant role players;
- 9.1.1.7 initiate and maintain regular communication with relevant role players;
- 9.1.1.8 draft annual reports on its activities and table such reports with the Director General and Minister of Health as appropriate.

9.2 Complaints, Advisory and Disciplinary Committee (CADC) is a standing committee of the NHREC

9.2.1 Terms of Reference: CADC must

- 9.2.1.1 set procedures for dealing with complaints (in terms of s 72(6)(d) of the NHA);
- 9.2.1.2 recommend investigation and possible disciplinary action by the relevant institution against a person or REC alleged to be in violation of norms and standards or guidelines for the ethical conduct of health research;
- 9.2.1.3 refer violations of professional rules by health care providers to the relevant statutory health professions councils.

9.3 Quality Promotion and Enhancement (QPEC) is a standing committee of the NHREC

9.3.1 Terms of Reference: QPEC must

9.3.1.1 develop criteria for registration of Research Ethics Committees including Animal Ethics Committees (all referred to as RECs) in South Africa; the criteria should be based on the Department of Health's Ethics in Research Guidelines (latest version) and other internationally recognised guidelines;

9.3.1.2 oversee registration and audit of Research Ethics Committees (RECs) in South Africa (including Animal Ethics Committees);

9.3.1.3 maintain a publicly accessible register of South African RECs;

9.3.1.4 carry out on-site audits as appropriate for quality control purposes;

9.3.1.5 monitor and evaluate annual reports from RECs;

9.3.1.6 facilitate ongoing research ethics review capacity building in South Africa.

9.4 Working Groups

9.4.1 Working Groups (WGs) may be established to advise the NHREC on any matter under consideration (Regulation 7(1))

9.4.2 Membership constitutes four to five persons, usually NHREC members, but may include co-opted persons with relevant expertise.

9.4.3 EXCO appoints the WG Chair who assumes the leadership role, identifies tasks and timelines, and institutes a modus operandi in order to fulfill the group's mandate; The Chair must be a member of the NHREC (Regulation 7(2)).

9.4.4 EXCO appoints a dedicated member of the Secretariat to each working group for administrative and logistical support.

9.4.5 WGs usually communicate electronically but the Chair may convene meetings as and when necessary.

9.5 Legal and Regulatory WG (LRWG)

9.5.1 Terms of Reference: LRWG must

9.5.1.1 ensure appropriate protection of human research participants by auditing the legal and regulatory framework to identify the potential need for legal and regulatory changes;

9.5.1.2 ensure best practice is publicised in the legal and regulatory framework;

9.5.1.3 raise awareness of the legal and regulatory framework;

9.5.1.4 advocate for change to the legal and regulatory framework to enhance protection of participants as appropriate.

9.6 Norms and Standards WG (NSWG)

9.6.1 Terms of Reference: NSWG must

- 9.6.1.1 set norms and standards (in terms of s 72(6)(c) of the NHA) for conducting research involving human participant and use of animals, including norms and standards for conducting clinical trials;
- 9.6.1.2 raise awareness of the ethico-legal normative framework that guides health research;
- 9.6.1.3 facilitate research ethics education through interaction with entities like SARIMA, SARETI and ARESA, through recommending appropriate online research ethics training and through publicising recommended guidance on the NHREC website;
- 9.6.1.4 respond to queries from RECs.

9.7 Health Research using Animals WG (HRAWG)

- 9.7.1 Terms of Reference: HRAWG must
 - 9.7.1.1 set norms and standards for conducting human health-related research using animals;
 - 9.7.1.2 promote the principles of replacement, reduction and refinement in animal research;
 - 9.7.1.3 ensure ethical and scientific integrity of health research using animals;
 - 9.7.1.4 facilitate awareness of the ethico-legal framework for research using animals;
 - 9.7.1.5 promote awareness of best practice in animal research ethics;
 - 9.7.1.6 audit latest developments in review processes and research related to use of animals.