CONSTITUTION OF

THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

Adopted at Pretoria on the 17th day of November 2010 at a full meeting of the National Health Research Ethics Council 2010-12 appointed in terms of the National Health Act (Act 61 of 2003)

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THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

1. Preamble

The National Health Research Ethics Council acknowledges that health research in the Republic of South Africa is conducted within the following framework:

- The National Health Act which seeks to "unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa; provide for a system of cooperative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality healthcare services; establish a health system based on decentralized management, principles of equity, efficiency, sound governance, ***internationally recognized standards of research and a spirit f enquiry and advocacy which encourages participation***; and, promote a spirit of cooperation and shared responsibility among public and private healthcare professionals and providers and other relevant sectors within the context of national, provincial and district health plans".[1]
- Health Research Policy in South Africa which seeks to "provide an enabling framework for the conduct of research that improves human health and wellbeing in South Africa" by promoting "research that contributes towards the improvement of human health and welfare in South Africa". Its goals are "to develop a national health research system that contributes to equitable health development; to promote innovation in health and health related service delivery; through research advance knowledge that underpins health and equitable, quality health care; to develop a co-ordinated, well funded agenda for research; to nurture talent and develop capacity to conduct research and utilise its findings; and, to encourage uptake of research-based knowledge into the health care system".[2]
- The Health Charter which seeks to engender the transformation of the health sector specifically in terms of access, equity, quality and broad based black economic empowerment in health services to meet the various healthcare needs of the entire South African population[3].
- The National Department of Health Strategic Plan 2010/11 – 2012/13 which implements a 10-point plan aimed at creating a well-functioning health system capable of producing improved health outcomes consisting of 20 deliverables in 4 key areas, viz., increasing life expectancy, combating HIV and AIDS, decreasing the burden of diseases from tuberculosis, and, improving health systems effectiveness. [4]
- The Declaration of Helsinki by the World Medical Association which is "a statement of ethical principles to provide guidance to physicians and other participants in

[1] http://www.info.gov.za/view/DownloadFileAction?id=68039
[2] http://www.doh.gov.za/docs/policy/healthresearch-2001.pdf.
[3] http://www.doh.gov.za/docs/misc/healthcharter.pdf
[4] http://www.doh.gov.za/docs/misc/stratplan/201011-201213a/index.html

medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data."[5]

2. **Definitions**

- **"Animal"** refers to all animals having the power of sense perception or sensation. "Any live, sentient non-human vertebrate, including eggs, fetuses and embryos, that is fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, wildfire and higher invertebrates such as the advanced members form the Cephalopoda and Decapoda"
- **"Animal research"** means the conducting of research on animals for human health research benefit.
- **"Clinical trials"** means a systematic study, involving human subjects that aims to answer specific questions about the safety or a medicine or method of treatment.
- **"Constitution"** means the Constitution of the Republic of South Africa, 1996 (Act No. 108 of 1996);
- **"Council"** means the National Health Research Ethics Council established under section 72 of the Act;
- "**Experimental animal**" refers to non-human vertebrates and non-human vertebrate fetuses which are bred or acquired for the sole purpose of use as an animal experiment
- **"Experiment"** – means any procedure whereby an animal is used in experiments for the purposes of the advancement of knowledge, to test a hypothesis, to supply a product, to provide organs, tissues or sera, to act as a host, to impart or demonstrate existing knowledge, to teach or learn surgical and other techniques, to comply with statutory requirements for testing or collecting data on any substance or product and to make audiovisual recordings of any of the above
- **"Health research"** includes any research which contributes to knowledge of-
    - the biological, clinical, psychological or social processes in human beings;
    - improved methods for the provision of health services;
    - human pathology;
    - causes of disease;
    - the effects of the environment on the human body;
    - the development or new application of pharmaceuticals, medicines and related substances;
    - the development of new applications of health technology;
- **"Health research"** means research into aspects of human health as defined in the National Health Act.
- **"Health research ethics committee"** means any committee registered in terms of *20* section 73;
- **"Level 1 research ethics committee"** means RECs that have the capacity to assess straightforward research designs that involve minimal risk to human participants. These include health research proposals that no not involve drug research, biomedical research involving human tissue, high budget research and high-technology research;

[5] http://ohsr.od.nih.gov/guidelines/helsinki.html

- **"Level 2 research ethics committee"** means RECs that may review all types of health research proposals;
- **"National department"** means the national Department of Health; 15
- **"National Health Council"** means the Council established by section 22(1);
- **"National-health policy"** means all policies relating to issues of national health as approved by the Minister;
- **"National Health Research Committee"** means the Committee established in 69 (section terms of 1); 20
- **"National Health Research Ethics Council** ' means the Council established by section *72(* 1);
- **"Norm"** means a statistical normative rate of provision or measurable target outcome over a specified period of time;
- **"Registration"** means the process for ensuring that research ethics committees comply with the essential prerequisites that allows them to perform their functions as either Level 1 or Level 2 committees;
- **"Research ethics committee (REC)"** means a committee contemplated in section 73 of the Act;
- **"Secretariat"** means the Directorate responsible for research in the national Department of Health;
- **"Sentient Animal"** refers to all animals having the power of sense perception or sensation
- **"The Act"** means the National Health Act (Act no. 61 of 2003), and any word or expression to which a meaning has been assigned in that Act, shall have that meaning unless the context indicate otherwise.
- **"Working group"** means the working group within the council responsible for the registration and auditing of research ethics committees within South Africa.

3. Purpose

The Health Research Ethics Council (NHREC) established in terms of the National Health Act, Section 72[1] is a legislated national body responsible for ensuring that health research is conducted ethically according to international best practice and by oversight of the composition, competence and operations of Health Research Ethics Committees.

4. Terms of Reference

4.1 Determine guidelines for the functioning of health research ethics committees (RECs).
4.2 Register and audit health RECs.
4.3 Set norms and standards for conducting research on humans and animals and norms and standards for conducting clinical trials.
4.4 Adjudicate complaints about the functioning of health RECs and hear any complaint by a researcher who believes he or she has been discriminated against by a health REC.
4.5 Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider

4.6 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.
4.7 Advise the national department and provincial departments on any ethical issues concerning research.
4.8 Set up working groups/task teams/sub-committees to carry out its functions.

5. Membership

5.1 The Minister of Health shall appoint fifteen (15) persons to the NHREC, after consultation with the National Health Council from persons nominated by interested parties at the invitation of the Minister by notice in the gazette as follows:

- Nine (9) with extensive experience and knowledge in health research ethics
- A representative from the community
- A representative from the Department
- A representative of the pharmaceutical industry
- A representative from the Medicines Control Council
- A person with extensive knowledge in animal health research ethics, and,
- A person with extensive knowledge in law.

5.2 The Minister of Health shall further appoint the Chairperson and Vice-Chairperson
5.3 A member of the NHREC shall be appointed for a period of three (3) years but may be reappointed for one (1) or more further terms.
5.4 A member of the NHREC shall vacate his/her office if he/she resigns of if requested by the Minister for good cause to resign.
5.5 If a member of the NHREC vacates or dies, the Minister shall fill the vacancy by appointing a person in accordance with the relevant sub section for the unexpired portion of term of office of his/her predecessor.

6. Meetings of the NHREC

6.1 The full membership of the NHREC will meet four (4) times a year, dates of which will be determined at the last meeting of the preceding year.
6.2 A special meeting of the NHREC may be convened:

- by the chairperson at any time; or
- on written request signed by any of its members, stating clearly the purpose for which the meeting is requested; or
- on written request by the Minister.

6.3 A quorum of 50% plus one will apply.
6.4 A call for items for the agenda shall be issued by the Secretariat 30 days before the date of each meeting.
6.5 The agenda shall close 15 days prior to meeting and the agenda and supporting documents shall be distributed electronically 10 days prior to the meeting.
6.6 Items for the agenda shall be submitted in electronic format to the Secretariat.
6.7 Urgent items may be added to the agenda up to 3 days before a meeting. The member concerned shall be responsible for circulating any documentation to all members.

6.8 Decisions shall be taken by consensus. Should it be necessary to vote, decisions shall be taken on simple majority with the Chairperson having the casting vote in addition to his/her deliberative vote should the vote be equal.

6.9 A member of NHREC must recuse him/herself from discussions/deliberations or decisions in which s/he has a conflict of interest

6.10 Apologies for absence shall be submitted in writing to the Secretariat.

6.11 Emergency decisions shall be taken by the Executive. The full committee shall ratify these decisions at its next meeting.

6.12 All meetings shall be minuted.

6.13 Minutes shall be distributed to all members by the Secretariat no later than 30 days after the meeting.

7. The Executive Committee (EXCO)

7.1 EXCO Membership

The following office bearers will form the Executive:

- Chairperson
- Deputy Chairperson
- Chairpersons of working groups/task teams/sub-committees as appropriate
- NHREC Secretariat

Terms of Reference of the EXCO

The EXCO shall:

7.1.1 Be responsible for NHREC operations between scheduled meetings.

7.1.2 Oversee the functioning of the working groups/task teams/sub-committees.

7.1.3 Identify and/or approve specialists for co-option onto working groups/task teams/sub-committees as necessary.

7.1.4 Formulate a strategic plan for NHREC in consultation with all NHREC members.

7.1.5 Formalize relationships by way of Memoranda of Agreement/Understanding with key stakeholders such as the Medicines Control Council and professional bodies.

7.1.6 Ensure the visibility of NHREC and highlight its activities amongst relevant stakeholders.

7.1.7 Initiate and maintain regular communication with relevant stakeholders.

7.1.8 Consult, collaborate and cooperate with the National Health Research Committee as necessary.

7.1.9 Draft annual reports on its activities and table such reports with the Director General and Minster of Health as appropriate.

8. Working Groups

8.1 Working Group Composition and Operations

8.1.1 Working groups shall be constituted of four (4) – five (5) persons, ideally NHREC members, but may include co-opted persons, all with the expertise relevant to the task assigned to the working group.

8.1.2 EXCO shall appoint the working group chair who shall assume the leadership role, identify tasks and timelines and institute a modus operandi to fulfill its mandate. The Chair must be a member of the NHREC

8.1.3 EXCO shall appoint a dedicated member of the Secretariat to each working group for administrative and logistical support.

8.1.4 Electronic communication shall be the method of choice for working groups but the working group chair may convene meetings as and when necessary.

8.2 Working Group on Health Research on Animals

8.2.1 Purpose

To set norms and standards for conducting health research on animals.

8.2.2 Terms of Reference

- To ensure the ethical and scientific integrity of health research involving animal subjects.
- To set norms and standards for conducting human health-related research on animals.
- To formulated ethical guidelines and standards for health research on animals.
- To ensure compliance with the ethical principles for humane animal experimentation.
- To promote the principles of replacement, reduction and refinement in animal research.
- To facilitate an awareness of best practices in animal health ethics.
- To disseminate the latest developments in the field of ethical review and analysis as related to animal health.

8.3 Working Group on the Registration and Auditing of Research Ethics Committees

8.3.1 Purpose

To oversee the implementation of the registration and auditing of Research Ethics Committees (RECs) in South Africa.

8.3.2 Terms of Reference

- To develop of criteria to be used for registration of REC's, based on the South African Guidelines for Medical Research and other internationally recognized guidelines.;
- To call all REC's to register with the NHREC.

- To maintain a publicly accessible register of all RECs.
- To categorize and provisionally register RECs as eligible to perform Level1 or Level 2 ethical evaluations on the basis of initial submissions for registration.
- To performing on-site audits and categorize RECs on the basis of their structure and functioning as eligible to perform Level1 or Level 2 ethical evaluations.
- To enable non-registered RECs to become registered and Level 1 RECs to advance to Level 2 RECs.
- To conduct an annual review process.
- To facilitate capacity building capacity in ethics review of health research in South Africa

8.4 Working Group on the Regulations Related to and Protection of Vulnerable Human Research Participants

8.4.1 Purpose

To ensure and legislate as appropriate the protection of human research participants categorised as vulnerable groups.

8.4.2 Terms of Reference

- To ensure international best practice in the regulations related to human research participants, specifically those categorised as vulnerable groups
- To raise awareness of regulations amongst the relevant stakeholders.
- To set norms and standards for the protection of vulnerable groups (VGs) of participants in South African research, including but not limited to children/minors, mentally ill research participants, prisoners and other groups.
- To audit the ethical-legal framework to identify protections and gaps in protection in South African law, ethical guidelines and policies with regard to VGs; and to compare with selected international protections.
- To strengthen protections by advocating for changes to ethical-legal framework to enhance the protection of VGs.
- To assist key stakeholders like Research Ethics Committees to recognize and apply key ethical and legal norms relating to VGs, through, for example, the generation of a select number of brief legal memos or fact sheets, and publications in NHREC and REC newsletters.
- To raise awareness of ethical-legal protections for VGs through consultations, email discussion groups (where possible) and interacting with ethics education groups in South Africa like IRENSA, or SARETI etc.
- To recommend new measures for the protection of vulnerable groups such as additional monitoring of protections for VGs where appropriate.
- To identify representatives of vulnerable groups and their organisations for the implementation of all NHREC activities e.g. Child Rights Groups, National Community Advisory Board structures, Department of Correctional Services etc.

8.5 Working Group on Training

8.5.1 Purpose

- To establish basic competencies for research ethics training recommended/required of individuals who serve on Research Ethics Committees and for researchers conducting health research.

8.5.2 Terms of Reference

- To define the basic content of training required.
- To facilitate availability of training by approved commercial and higher education groups i.e. assist in getting other institutions to provide the training with the support from the Department of Health or fundraising to enable people to run the training.
- To liaise/interact with the NHREC working group on vulnerable groups working on new provisions to protect vulnerable research participants, to ensure that new guidelines are included in the training.
- To liaise with the Communication Subcommittee of NHREC to develop guidelines and strategies to work with various Public, Regional and Academic Ethics Committees.
- To investigate the feasibility of web-based/on-line training
- To facilitate the sharing of best practices in ethics training.

8.6 Working Group on Material Transfer

8.6.1 Purpose

To deliberate on the MTA document and the ethical issues pertaining to Human Tissue samples.

Terms of Reference

- To deliberate on the relevance of the MTA as a guidance to the NHREC
- To draft a discussion document on Human Tissue and Material transfer
- To make recommendations regarding possible guidelines or amendments to guidelines or regulations as needed.

8.7 Working Group on Complaints and Disciplinary Procedures

8.7.1 Purpose

To set guidelines for the National Health Research Ethics Council for dealing effectively with complaints regarding ethic of research on human or animal populations.

8.7.2 Terms of Reference

- To ensure the ethical and scientific integrity of biomedical research involving human/ animal subjects in the RSA.
- To put into place systems for addressing complaints from research participants, researchers and the public.
- To improve the quality of care in of participants in clinical trials.
- To adjudicate complaints about the functioning of Health RECs.
- To hear complaints by researchers who believe that they have been discriminated against by Health RECs.
- To institute disciplinary action against any person found to be in violation of norms and standards, or guidelines, set for conducting of health research in terms of the Act
- Refer to the relevant statutory health professional councils matters involving the violation or potential violation of a professional or ethical rule by a health professional or health care provider.