
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 839

23 September 2010

NATIONAL HEALTH ACT, 2003 (Act No.61 of 2003)

REGULATIONS RELATING TO THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

The Minister of Health has, after consultation with the National Health Council, in terms of section 90(s) read with section 72(2) of the National Health Act, 2003 (Act no. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

Definitions

1. In these regulations, "the Act" means the National Health Act, 2003 (Act no. 61 of 2003), and any word or expression, to which a meaning has been assigned in that Act, shall have that meaning and unless the context indicates otherwise:

"Animal research" means the conducting of research on animals for human health research benefit.

"Chairperson" means chairperson of the National Health Research Ethics Council;

“Committee” means the Health Research Ethics Committee referred to in section 73 of the Act;

“Council” means the National Health Research Ethics Council established in terms of section 72(1) of the Act;

“Department” means the National Department of Health;

“Medicines Control Council” means the Medicines Control Council established in terms of section 2 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); and

“Secretariat” means the staff in the Department providing technical and administrative support for the Council.

Constitution of the Council

2. The members of the Council appointed by the Minister in terms of section 72(2) (a) are constituted as follows:
 - (a) nine with extensive experience and knowledge in health research ethics;
 - (b) A representative from the community;
 - (c) A representative from the Department;
 - (d) A representative of the pharmaceutical industry;
 - (e) A representative from the Medicines Control Council;

- (f) A person with extensive knowledge in animal health research ethics; and
- (g) A person with extensive knowledge in law.

Nomination and appointment of members of the Council

3.(1) A notice relating to nominations of members of the Council shall be published in the Government Gazette and at least one newspaper enjoying circulation in the entire Republic for appointment referred to in section 72(2)(a) of the Act and shall include—

- (a) the closing date and time for the receipt of nominations, and
 - (b) an address to which the nominations should be sent or delivered.
- (2) A nomination of members of the Council must be in a form substantially similar to Annexure “A” and must be accompanied by a curriculum vitae signed by the nominated person.
- (3) If the Minister receives no nomination or receives an insufficient number of nominations within the period specified in the invitation, he or she may appoint the required number of persons who qualify to be appointed in terms of section 72(2) and such an appointment shall be deemed to have been appropriately made.

Appointment of the chairperson and the vice-chairperson

- 4.(1). For every newly constituted Council the Minister shall appoint the chairperson and a vice-chairperson.
- (2) The chairperson and vice-chairperson shall hold office during the term of office of the members of the Council unless the chairperson and the vice-chairperson shall sooner resign or cease to be a member of the Council.
- (3) The vice-chairperson may, if the chairperson is absent or for any reason unable to act as chairperson, perform all the functions and exercise all the powers of the chairperson.
- (4) If both the chairperson and vice-chairperson are absent from any meeting, the members present shall elect one of their number to preside at that meeting and the person so presiding may, during that meeting and until the chairperson and the vice-chairperson resumes duty, perform all the functions and exercise all the powers of the chairperson.
- (5) If both the chairperson and the vice-chairperson have been given leave of absence, the Minister shall appoint one of the members to act as chairperson until the chairperson and the vice-chairperson resumes duty or vacates office.
- (6) If the office of chairperson and the vice-chairperson become vacant, the Minister shall appoint a new chairperson and the vice-chairperson, as the case may be, and the member so elected shall hold office for the unexpired portion of the period for which his or her predecessor was appointed.

Meetings of the Council

- 5.(1) The first meeting of the Council shall be held within 30 days after the appointment of its members, at a time and place determined by the Secretariat, and all subsequent meetings shall be held at such time and place as may be determined by the Council.
- (2) At all meetings of the Council, the chairperson or in his or her absence the vice-chairperson, or in the absence of both the chairperson and the vice-chairperson, any other member of the Council designated by the members present, shall preside.
- (3) The Council must meet not less than four times annually for the purpose of conducting its business.
- (4) A special meeting of the Council may be convened—
- (a) by the chairperson at any time; or
 - (b) on a written request signed by any of its members, stating clearly the purpose for which the meeting is requested; or
 - (c) on a written request by the Minister.

Quorum, procedure at meetings and decision-making

- 6.(1) A quorum of any meeting of the Council is one half of the total number of its members plus 1.
- (2) The Council must determine the procedure to be followed at its meetings.

- (3) Members of the Council must treat all Council matters with confidentiality and must refrain from unreasonable disclosure of personal, private and sensitive information belonging to third parties.
- (4) The decision of the majority of the members of the Council present at any meeting thereof shall constitute a decision of the Council, and in the event of an equality of votes, the chairperson shall have a casting vote in addition to his/her deliberative vote.
- (5) Only members of the Council have the voting rights on any matter in which the Council is required to make a decision.
- (6) A decision taken by the Council or an act performed under the authority of the Council is not invalid merely by reason of—
 - (a) an interim vacancy in the Council; or
 - (b) the fact that a person who is not entitled to sit as a member of the Council, was present at the time when the decision was taken, if the act was authorized by the required majority members of the Council present at the time.
- (7) A member of the Council must recuse him or herself from discussions/deliberations or decisions in which he or she has a conflict of interest.

Working groups of the Council

- 7.(1) The Council may establish one or more working groups to advise it on any matter related to any subject matter under consideration.

- (2) The chairperson of a working groups referred to in sub-regulation (1) must be a member of the Council.
- (3) the term of office of a person appointed to a working group of the Council, will be determined by the task for which such working group was formed.
- (4) Members of working groups may be re-appointed.
- (5) Notwithstanding sub-regulations (3) and (4) above, membership to a working group may be terminated at any time by the chairperson of the Council on good cause shown.

Secretariat

8.(1) The Department will function as the secretariat for the Council.

(2) The Secretariat must—

- (a) render secretarial services to the Council and maintain the records of the Council's meetings;
- (b) ensure efficient and effective management of financial and administrative matters of the Council.
- (c) in a format and for periods as may be determined by Council, report to the Council on all expenditures incurred by the Council including travel, accommodation, subsistence and other allowances; and
- (d) provide the Council with the administrative and technical support, resources and information necessary for the performance of its functions.

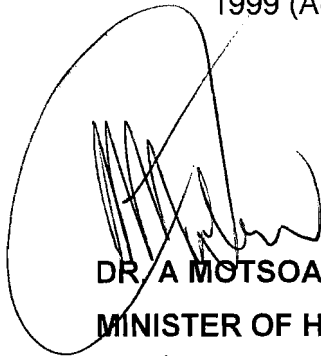
Appeals

- 9.(1) A person who is aggrieved by a decision of the Council may appeal against such decision and shall inform the Minister in writing within 60 days of such a decision having come to the knowledge of that person.
- (2) Such an appeal must clearly state—
- (a) the decision against which such appeal is lodged; and
 - (b) the grounds on which such appeal is lodged.
- (3) The Minister must appoint an appeals committee that consists of no fewer than three persons, constituted as follows:
- (a) the chairperson, appointed on account of his or her knowledge of the law; and
 - (b) two other members appointed on account of their skills and knowledge of health research ethics matters.
- (4) No member of an appeals committee shall have a direct or indirect interest in the affairs of the appellant or respondent.

Remuneration

- 10.(1) Members of the Council shall be remunerated according to scales determined and approved by National Treasury.

- (2) A government official who is a member of a working group or an appeals committee may not receive additional remuneration from the Department.
- (4) A non-government official who is a member of the working group/s or appeals committee shall be remunerated according to scales determined and approved by the National Treasury.
- (5) Travel and accommodation expenses of members of the Council, appeals committee and working groups will be paid by the Department within the applicable provisions of the Public Finance Management Act, 1999 (Act No. 1 of 1999) and Treasury Regulations.



DR. A MOTSOALEDI, MP
MINISTER OF HEALTH

29/10/2009

ANNEXURE A**NOMINATION FORM: NATIONAL HEALTH RESEARCH ETHICS COUNCIL**

This nomination form should be used for the nomination of persons contemplated in regulation 2

We, the undersigned,

1.

.....

.....

.....

(full names and address)

2.

.....

.....

.....

(full names and address)

declare that we represent / are members of:

..... and

hereby nominate, as a candidate for nomination as a member of the National Health Research Ethics Council,

.....

who holds the title of and is employed as a

..... and is a South African citizen/

not a South Africa citizen but is a permanent resident of South Africa*.

Signed at on 20

1.(Signature)

2.(Signature)

.....

Signed in the presence of the following witnesses:

.....

Signature:.

Full Names:

Signature:.

Full Names:.

..... (full)

I, the undersigned, name(s), hereby consent to my nomination as a candidate for nomination as a member of the National Health Research Ethics Council.

Signed at **on** **20**.....

.....

(Signature)

.....

.....

.....

.....

(Registered address and contact details)

Signed in the presence of

Signature:.

Name:

The following witnesses:

.....

.....

.....

.....

*** Delete whichever is not applicable**