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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 person 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 MOTSOLEDI, 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**

KITSISO YA PUSO

LEFAPHA LA BOITEKANELO

No. R. 839

23 September 2010

**MOLAO WA BOSETŠHABA WA BOITEKANELO WA 2003
(MOLAO WA NO 61 WA 2003)****MELAWANA E E MABAPI LE KHANSELE YA BOSETŠHABA YA
BOITEKANELO YA DIKAELO TSA PATLISISO**

Tona ya Boitekanelo o ne a dira melawana mo mametlelelong, morago ga go rerisana le Khansela ya Bosetšhaba ya Boitekanelo, go ya ka karolo 90 (s) e e buisiwang le karolo 72 (2) ya Molao wa Bosetšhaba wa Boitekanelo wa 2003 (Molao wa no. 61 wa 2003).

MAMETLELELO**Ditlhaloso**

1. Mo melawaneng e, "Molao" o kaya Molao wa Bosetšhaba wa Boitekanelo wa 2003 (Molao wa no. 61 wa 2003), mme lefoko lengwe le lengwe kgotsa tlhagiso e e dirisitsweng mo Molaong, e tla nna le bokao joo ntle fela fa bokao bo supa ka tsela nngwe:

"Patlisiso ya diphologolo" e kaya go dira patlisiso ka ga diphologolo go thusa patlisiso ya boitekanelo jwa batho

“Monnasetulo” e kaya monnasetulo wa Khansele ya Bosetšhaba ya Boitekanelo ya Dikaelo tsa Patlisiso ;

“Komiti” e kaya Komiti ya Bosetšhaba ya Boitekanelo ya Dikaelo tsa Patlisiso e e kaiiweng mo karolong 73 ya Molao;

“Khansele” e kaya Khansele ya Bosetšhaba ya Boitekanelo ya Dikaelo tsa Patlisiso e e tlhomilweng go ya ka karolo 72 (1) ya Molao;

“Lefapha” le kaya Lefapha la Bosetšhaba la Boitekanelo;

“Khansele ya Taolo ya Melemo” e kaya Khansele ya Taolo ya Melemo e e tlhomilweng go ya ka karolo 2 ya Molao wa Melemo le

“Bokwaledi” bo kaya badiri ba Lefapha ba ba tlamelang tshegetso ya setegeniki le tsamaiso mo Khanseleng.

Molaotheo wa Khansele

2. Ditokololo tsa Khansele tse di thapilweng ke Tona go ya ka karolo 72 (2) di tlhamilwe ka tsela e e latelang:

(a) *robongwe, ka maitemogelo a a tseneletseng le kitso mo patlisisong ya dikaelo tsa boitekanelo; ;*

(b) *kemedi go tswa mo setšhabeng;*

(c) *Kemedi go tswa mo Lefapheng;*

(d) *Kemedi go tswa mo indasetering ya khemise;*

- (e) Kemedi go tswa mo Khanseleng ya Taolo ya Melemo;
- (f) Motho yo o nang le kitso e e tseneletseng mo patlisisong ya dikaelo tsa boitekanelo jwa diphologolo, le
- (g) *Motho yo o nang le kitso e e tseneletseng ya molao..*

Tlhagiso le thapo ya ditokololo tsa Khansele

- 3.(1) Kitsiso e e mabapi le tlhagiso ya ditokololo tsa Khansele e tla phasaladiwa mo Gaseteng ya Puso mme bonnye ke lokwalodikgang le le lengwe le le tla anamisetsang Rephaboliki yotlhe ka thapo e e kailweng mo karolo 72 (2) (a) ya Molao mme e tla akaretsa-

- (a) *letlha le nako ya go tswala kamogelo ya ditlhagiso; le*
- (b) *aterese e ditlhagiso di tshwanetseng go romelwa go yona.*

- (2) Tshisinyo ya ditokololo tsa Khansele e tshwanetse go nna ka mokgwa o o tshwanang thata le Mametlelelo "A" mme e tshwanetse go tla le curriculum vitae e e saenilweng ke motho yo o tshisintsweng.
- (3) Fa Tona a sa amogele tshisinyo kgotsa a amogela palo e e kwa tlase ya ditshisinyo mo nakong e e totobaditsweng ya taletso, a ka thapa palo ya batho ba ba tlhokegang ba ba siamelwang ke go thapiwa go ya ka karolo 72 (2) mme thapo ya go nna jalo e tla tsewa e le maleba.

Thapo ya Monnasetulo le Motlatsamonnasetulo

- 4.(1). Tona o tla thapa monnasetulo le motlatsamonnasetulo mo Khanseleng nngwe le nngwe e ntshwa e e tlhamiwang.
- (2) Monnasetulo le motlatsamonnasetulo ba tla nna mo ofising mo pakeng ya ofisi ya ditokololo tsa Khansele ntle fela fa monnasetulo kgotsa motlatsa monnasetulo a ka leboga tiro go sa le gale kgotsa a khutla go nna tokololo ya Khansele.
- (3) Motlatsamonnasetulo a ka dira ditiro tsotlhe le go diragatsa dithata tsa monnasetulo tsotlhe fa monnasetulo a ka se nne gone kgotsa a sa kgone go nna monnasetulo ka lebaka lengwe le lengwe.
- (4) fa bobedi jwa bona ba se teng kwa kopanong nngwe le nngwe, ditokololo tse di teng di tla tlhopa mongwe wa bona go tsamaisa kopano mme motho yo o tsamaisang kopano ka nako eo le go fitlhela monnasetulo le motlatsamonnasetulo ba boela kwa tirong, a ka dira ditiro tsotlhe le go diragatsa dithata tsa monnasetulo.
- (5) Fa monnasetulo le motlatsamonnasetulo ba neilwe malatsi Tona o tla thapa mongwe wa ditokololo go nna mo boemong jwa monnasetulo go fitlha monnasetulo le motlatsamonnasetulo ba simolola tiro kgotsa ba tlogela ofisi.
- (6) Fa ofisi ya monnasetulo le motlatsamonnasetulo di nna lolea, Tona o tla thapa monnasetulo le motlatsamonnasetulo ba ba ntshwa, fa go le jalo, tokololo e e tlhopilweng jalo e tla nna mo ofising mo karolong ya nako e e seng e fele ya monnasetulo yo o thapilweng pele ga gagwe.

Dikopano tsa Khansele

- 5.(1) Kopano ya pele ya Khansele e tla tshwarwa mo malatsing a le 30 morago ga go thapiwa ga ditokololo tsa yona, ka nako le lefelo le le tlhomamisitsweng ke Bokwaledi, mme dikopano tsotlhe di tla tshwarwa ka nako le lefelo leo le le tla tlhomamisiwang ke Khansele.
- (2) Kwa dikopanong tsotlhe tsa Khansele, monnasetulo kgotsa fa a se gone motlatsamonnasetulo, kgotsa tokololo nngwe le nngwe e e tlhopilweng ke ditokololo tse di leng teng, o tla tsamaisa kopano.
- (3) Khansele e tshwanetse go kopana eseng bonnye jwa gane ka ngwaga ka maitlomo a go dira tiro ya yona.
- (4) Kopano e e kgethegileng ya Khansele e ka rulagangwa-
- (a) ke monnasetulo nako nngwe le nngwe, kgotsa
 - (b) ka kopo e e kwadilweng mme e saenilwe ke mongwe le mongwe wa ditokololo tsa yona, e e kayang ka botlalo maitlomo a kopano e kopiwang ka ona, kgotsa
 - (c) ka kopo e e kwadilweng ke Tona.

Khoramo, tsamaiso kwa dikopanong le go dira ditshwetso

- 6.(1) Khoramo ya kopano nngwe le nngwe ya Khansele ke halofo e le nngwe ya palogotlhe ya palo ya ditokololo tsa yona le motho a le mongwe.
- (2) Khansele e tshwanetse go tlhomamisa tsamaiso e e tshwanetseng go latelwa kwa dikopanong tsa yona.

- (3) Ditokololo tsa Khansele di tshwanetse go tshwara dilo ka bophiri mme di tshwanetse go thibela go senola tshedimosetso e e poraefete, e e bopihiri ya batho ba bangwe.
- (4) Tshwetso ya bontsi jwa ditokololo tsa Khansele tse di leng teng kwa kopanong nngwe le nngwe ya yona e tla tlhama tshwetso ya Khansele, mme fa divoutu di lekana, monnasetulo o tla nna le voutu go tlaletsa voutu ya gagwe ya therisano.
- (5) Ke ditokololo tsa Khansele fela tse di nang le ditshwanelo tsa go vouta mo go sengwe le sengwe se Khansele e tlhokang go dira tshwetso mo go sona.
- (6) Tshwetso e e tsellweng ke Khansele kgotsa tiro e e dirilweng ka taolo ya Khansele ga e na go tsewa e sa siama ka lebaka fela la-
 - (a) phatlhatiro ya nakwana mo Khanseleng; kgotsa
 - (b) gonne motho yo o sa tshwanelang mo nna tokololo ya Khansele, o ne a le teng ka nako e tshwetso e ne e tsewa ka yona, fa kgato e dumeletswe ke bontsi jo bo tlhokegang jwa ditokololo tse di teng ka nako eo.
- (7) Tokololo ya Khansele e tshwanetse go ikogela morago mo dipuisanong/therisanong kgotsa ditshwetso fa a nang le kgotlhang ya dikgatlhego gone.

Ditlhophha tse di dirang tsa Khansele

- 7.(1) Khansele e ka tihoma ditlhophha tse di dirang tse di fetang nngwe go e gakolola ka sengwe le sengwe se se mabapi le morero mongwe le mongwe o o sekasekwang.
- (2) Monnasetulo wa setlhophha se se dirang se se kailweng mo molawaneng (1) o tshwanetse go nna tokololo ya Khansele.
- (3) paka ya ofisi ya motho yo o thapilweng mo setlhophheng sa tiro e tla tlhomamisiwa ke tiro e setlhophha se se tlhodilweng ka yona.
- (4) Ditokololo tsa ditlhophha tse di dirang di ka thapiwa gape.
- (5) Go sa kgathalesege melawanapotlana (3) le (4) e e kwa godimo, botokololo jwa setlhophha se se dirang bo ka khutlisiwa nako nngwe le nngwe ke monnasetulo wa Khansele fa lebaka le le siameng le bontshitswe. ,

Bokwaledi

- 8.(1) Lefapha le tla dira jaaka bokwaledi jwa Khansele. .
- (2) Bokwaledi bo tshwanetse go-
 - (a) *tlamela ditirelo tsa bokwaledi mo Khanseleng le go tshwara direkoto tsa dikopano tsa Khansele.*
 - (b) *netefatsa tsamaiso e e kgonang e e nonofileng ya merero ya ditshelete le tsamaiso ya Khansele.*

- (c) *ka mokgwa le dinako tse di ka tlhomamisiwang ke Khansese, begela Khansese ka ditshenyegelo tse di itemogetsweng ke Khansese go akaretsa maeto, manno, boitshediso le ditetlo tse dingwe; le*
- (d) *tlamela Khansese ka tshegetso ya tsamaiso le ya setegeniki, didinisiwa le tshedimosetso e e tlhokegang go diragatsa ditiro tsa yona.*

Boikuelo

- 9.(1) **Motho yo o utlwisitsweng botlhoko ke tshwetso ya Khansese a ka ikuela kgatlhano le tshwetso eo mme o tla itsise Tona ka go mo kwalela mo malatsing a le 60 morago ga go itse ka ga tshwetso eo.**
- (2) **Boikuelo joo bo tshwanetse go kaya ka botlalo—**
 - (a) **tshwetso e boikuelo bo tlhomiwang kgatlhanong le yona; le**
 - (b) **mabaka a go tlhoma boikuelo a diriwang ka ona**
- (3) **Tona o tshwanetse go thapa komiti ya boikuelo e nang le batho ba ba seng ka fa tlase ga tharo, mme bona batla tlhamega ka tsela e e latelang:**
 - (a) **monnasetulo o thapiwa go ya ka kitso ya gagwe ya molao; le**
 - (b) **ditokololo tse dingwe di le pedi tse di thapiwang go ya ka bokgoni jwa bona le kitso ya dilo tsa patlisiso ya dikaelo tsa boitekanelo**
- (4) **Ga go tokololo ya komiti ya boikulelo e e tla nnang le kgatlhego e e lebaneng kgotsa e sa lebanang mo mererong ya moikuedi kgotsa moamegi.**

Tuelo

- 10.(1)** Ditokololo tsa Khansele di tla duelwa go ya ka dikale tse di tihomamisitsweng le go amogelwa ke Bobolokelo jwa Bosetšhaba.
- (2) Modiredipuso yo e leng tokololo ya setlhopha se se dirang kgotsa ya komiti ya boikuelo a ka se amogele tuelo ya tlaleletso go tswa mo Lefapheng.
- (4) Motho yo e seng modiredipuso yo e leng tokololo ya setlhopha se se dirang kgotsa ya komiti ya boikuelo o tla duelwa go ya ka dikale tse di tihomamisitsweng le go amogelwa ke Bobolokelo jwa Bosetšhaba.
- (5) Ditshenyegelo tsa maeto le manno tsa ditokololo tsa Khansele, komiti ya boikuelo le ditlhopha tse di dirang di tla duelwa ke Lefapha mo ditlamelong tse di maleba le Molao wa Tsamaiso ya Ditšhelete tsa Puso, 1999 (Molao wa No.1 wa 1999) le Melawana ya Matlotlo.

NGK. A MOTSOLEDI, MP
TONA YA BOITEKANELO

MAMETLELELO YA A

**FOROMO YA TSHISINYO: KOMITI YA BOSETŠHABA YA BOITEKANELO YA
PATLISISO**

Foromo e e tshwanetse go dirisetswa tshisinyo ya batho ba ba akantsweng mo
molawaneng wa bo 3

Rona , ba ba saenileng kwa tlase,

1.
.....
.....
.....

(maina a a feletseng le aterese)

2.
.....
.....
.....

(maina a a feletseng le aterese)

Itsise gore re emetse/re ditokololo tsa:

..... mme re
tshisinya, jaaka ntlhopheng wa tshisinyo , jaaka tokolololo ya Komite ya
Boitekanelo ya Patlisiso,

.....
yo o nang le maemo a mme a thapilwe jaaka
..... mme ke moagi wa Aforika
Borwa ; ga se moagi wa Aforika Borwa fela ke monni wa leruri wa Aforika
Borwa*.

E saenilwe mo ka di 20

1.(Tshaeno)

2.(Tshaeno)

E saenilwe fa pele ga dipaki tse di latelang:

Tshaeno:.

Maina a a Feletseng:

Tshaeno:.. ..

Maina a a Feletseng:.. ..

Nna, yo o saenilweng kwa tlase, leina kgotsa maina, ke dumela tshisinyso ya me jaaka ntlhopheng wa tshisinyo jaaka tokololo ya Komiti ya Bosetšhaba ya Boitekanelo ya Patlisiso .

E saenilwe mo ka di..... 20...

(Tshaeno)

(Aterese e e kwadisitsweng le ditlha tsa kgolagano)

E Saenilwe fa pele ga

Tshaeno:

Leina:

Dipaki tse di latelang:

* Phimola tse di seng maleba