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## GOVERNMENT NOTICE

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### DEPARTMENT OF HEALTH

No. R. 378

29 May 2013

#### NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

#### REGULATIONS RELATING TO RESEARCH ON HUMAN SUBJECTS

The Minister of Health has, in terms of section 71 read with section 90(1) of the National Health Act, 2003 (Act No. 61 of 2003) made the regulations in the schedule.

Interested persons are invited to submit written comments on the proposed regulations, or any representations they wish to make in regard thereto, to the Director-General: Health, Private Bag x828, Pretoria, 0001 (for the attention of the Director: Health Systems Research within two months of the date of publication of this notice).

#### SCHEDULE

##### Definitions

1. In these regulations “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 indicates otherwise—

“**best interests**” means significant decisions affecting a minor’s life should aim to promote amongst others the minor’s physical, mental, moral and emotional welfare ;

“**condition**” means physical and psycho-social characteristics shown to affect health;

“**Council**” means the National Health Research Ethics Council established under section 72 of the Act;

**“Human subject”** means a living person about whom an investigator obtains data or specimens or identifiable private information through intervention or interaction with that person;

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

**“minimal risk”** means the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life including routine medical, dental or psychological tests or examinations;

**“non-therapeutic research”** means research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalizable knowledge;

**“research ethics committee”** means a committee contemplated in section 73 of the Act;

**“significant risk”** means substantial risk of serious harm;

**“therapeutic research”** means research that holds out the prospect of direct benefit to the participant;

**“vulnerable persons”** means those persons whose context exposes them to conditions that increase their risk of harm, or limits their freedom to make choices.

### **Principles of health research**

2. Any form of health research conducted in South Africa, which involves the participation of human subjects, must—

(a) be relevant both to the overall health and developmental needs of the population of the Republic, or the individual needs of those who suffer from the disease and/ or concerns and subject matter of the study;

(b) have a valid scientific methodology and a high probability of providing answers for the specific research questions that are posed;

(c) be managed and conducted by a suitably qualified principal investigator who is experienced in the field of health research;

- (d) ensure that research participants are well informed and able to make appropriate choices;
- (e) be undertaken with informed consent of the participant or their legally authorised representative;
- (f) ensure that participants' rights are respected, including but not limited to rights to dignity, privacy, bodily integrity and equality;
- (g) ensure that the recruitment and selection process is just and fair;
- (h) be preceded by a favourable risk-benefit analysis;
- (i) undergo independent review by a registered research ethics committee; and
- (j) be registered in the South African National Clinical Trials Register, if classified as a clinical trial.

### **Obligations of researchers**

**3.** A researcher conducting research involving human subjects is obliged to—

- (a) submit their research proposals for review and approval to a registered research ethics committee and where applicable, to the Medicines Control Council or any other body required by law;
- (b) where necessary, consult with and notify the affected institutional or governmental authorities;
- (c) disclose the sources and extent of funding for the research to participants and to the research ethics committee;
- (d) ensure safety monitoring of participants and manage harm experienced by participants;
- (e) in the case of harm, refer participants for professional assistance if such assistance is available;
- (f) ensure that compensation for research-related injury is available, in the event of more than minimal risk research; and

(g) disseminate research results, whether negative or positive, to research stakeholders, in a timely and competent manner including to participants and participating communities as far as possible.

**Participation of special classes of persons in research studies**

4(1) Minors may only participate in research in instances where—

- (a) the research poses a minimal risk to the minor; or
- (b) the research poses more than minimal risk, but holds out the prospect of direct benefit to the minor concerned; or
- (c) the research poses a minor increase over minimal risk, and holds out no prospect of direct benefit to the minor but will yield generalisable knowledge about the condition under study; and
- (d) the minor's participation is indispensable to the research.

(2) Research involving persons with intellectual or mental impairment must—

- (a) strictly focus on mental disability to necessitate the involvement of persons who are mentally disabled;
- (b) have suitable evaluation procedures to assess whether the participant is capable of giving informed consent;
- (c) obtain consent from the research participant where possible; or alternatively consent must be obtained from the legally appropriate person and assent from the research participant;
- (d) ensure that consent is free from coercion; and
- (e) ensure that the research poses:
  - (i) minimal risk; or
  - (ii) more than minimal risk, but holds out the prospect of direct benefit to the participant; or

- (iii) a minor increase over minimal risk, and holds out no prospect of direct benefit but will yield generalisable knowledge about the condition under study.

(3) In approving proposals for research, special attention should be given to the vulnerability of persons who are in dependent relationships or comparable situations including but not limited to:

- (a) older persons and their care-givers;
- (b) patients and health-care professionals;
- (c) students and teachers;
- (d) persons with life-threatening diseases and their care-givers;
- (e) wards of the state and guardians or care-givers;
- (f) employees and employers;
- (g) prisoners and the relevant prison authorities; and
- (h) members of the South African National Defence Force and their superiors.

(4) When approving research proposals, extra attention should be given to research involving women, and in particular—

- (a) the exclusion of women from research studies should be scientifically justified;
- (b) no research activities involving pregnant women and fetuses may be undertaken unless:
  - (i) appropriate studies on animals and non-pregnant individuals have been completed;
  - (ii) the purpose of the activity is to meet the health needs of the mother of that particular foetus or the foetus itself; or
  - (iii) the risk to the foetus is minimal, or in all cases, is the least possible risk for achieving the objectives of that activity.

**Other types of research that need additional consideration**

5(1) Research on vulnerable persons must be evaluated with caution, to ensure that—

(a) persons in those communities would not unnecessarily be involved in research that could be carried out in non-vulnerable communities; and

(b) the research is responsive to the health needs and the priorities of the community in which it is carried out.

(2) Participants involved in indigenous medical systems research must be subject to the same degree of respect and protection from harm as participants in scientific medical research.

(3) Research involving innovative therapy or intervention must make appropriate provision for long-term care and observation of participants.

(4) Research studies involving prisoners must—

(a) be undertaken in accordance with guidelines issued by the Department of Correctional Services;

(b) present risks commensurate with risks that would be accepted by non-prison volunteers;

(c) ensure protection of the rights of prisoners, including the right to dignity and humanity of the prisoners; and

(d) facilitate the ability of prisoners, both sentenced and awaiting trial, to make voluntary decisions about research participation.

**Informed Consent**

6. Persons with whom research is to be conducted, or their legally authorised representative, have the right to be informed of—

(a) the purpose of the research;

- (b) treatments and possibility of random assignment of each treatment (if the research involves treatment);
- (c) methods and procedures to be followed or used during the research;
- (d) alternatives apart from participating in the research;
- (e) potential harms and risks involved in participation;
- (f) expected benefits to the participant and other persons in the research;
- (g) extent to which confidentiality and privacy will be maintained;
- (h) available insurance in the event of research-related injury, for more than minimal risk research;
- (i) details of the contact person in the event of a query or research related injury;
- (j) reimbursement and/or incentives given for participation;
- (k) in cases of clinical trials, the availability of treatment beyond the duration of the trial;
- (l) details of the sponsor and any potential conflict of interests;
- (m) their freedom to decline or withdraw from the research without prejudice; and
- (n) proof of ethics committee approval or MCC approval, where relevant.

#### **Review of Research Proposals by Research Ethics Committees**

7. All health research studies involving human subjects must—

- (a) be reviewed by a research ethics committee which is registered with the Council;
- (b) satisfy the requirements as determined by such a Committee; and
- (c) adhere to the recommendations made by the Committee.

**Ministerial consent for non-therapeutic research**

8(1) Health research protocols that are classified as non-therapeutic research with minors must obtain ministerial consent in terms of s71(3)(a)(ii) of the Act, or where appropriate consent from a duly appointed delegated authority in terms of s92(a) of the Act.

(a) applications for ministerial consent must be made by investigators in the form of Form A;

(b) such applications should be considered by the Minister or the delegated authority after the protocol has been reviewed by a registered research ethics committee and is found to meet the ethical standards of that committee as stated in terms of s 73(2)(b) of the Act;

(c) in granting Ministerial Consent, relevant bodies including the National Health Research Ethics Council, or relevant experts, may be consulted;

(d) Ministerial Consent may be granted or refused; and

(e) the investigator shall be notified of the outcome in a timely manner.

**Commencement of regulations**

9. These regulations come into operation on the date of publication.



Dr A Motsoaledi, MP

MINISTER OF HEALTH

Date:

14/4/2013

**FORM A****DEPARTMENT OF HEALTH****APPLICATION FOR MINISTERIAL CONSENT  
FOR NON-THERAPEUTIC RESEARCH WITH MINORS****1 INSTRUCTIONS**

1. This application form shall be completed for all protocols that are classified as “non-therapeutic” and involve the participation of minors.

*Non therapeutic research is defined in the regulations relating to research on Human Subjects as “research that does not hold out the prospect of direct benefit but holds out the prospect of generalizable knowledge”. Minors are defined as persons under the age of 18 by section 17 of the Children’s Act (No. 38 of 2005).*

2. This application form should be submitted with a copy of the protocol and supporting documents.
3. This application should be submitted to the Minister of Health or the delegated authority in terms of s92(a) of the Act.
4. This application form should describe how ‘non-therapeutic’ research protocols with minors meet the conditions set out in s71 (3) (b) of the Act (described below).
5. All sections of the form must be completed in full.
6. Ministerial Consent may only be granted for non-therapeutic health research with minors when certain conditions set out in section 71 (3) (b) of the Act are met. These conditions are:
  - i. The research objectives cannot be achieved except by the enrolment of minors;
  - ii. The research is likely to lead to an improved scientific understanding of conditions, or disorders affecting children;
  - iii. Any consent given to the research must be in line with public policy; and
  - iv. The research does not pose a significant risk to minors, and if there is some risk, the benefit of the research outweighs the risk.

Name of principal investigator: \_\_\_\_\_

Institutional affiliation of the principal investigator:

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Postal address:

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Physical address:

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Email address:

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Phone:

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Fax:

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Title of research protocol:

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\_\_\_\_\_

Date of application:

Signature of the applicant: \_\_\_\_\_

### 3. APPLICATION

**3.1: Condition 1: The research objectives cannot be achieved except by the participation of minors**

*Describe the scientific justification for the enrolment of minors:*

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**3.2: Condition 2: The research is likely lead to an improved scientific understanding of certain conditions, diseases or disorders affecting minors**

*Describe how the research will advance knowledge affecting the health and welfare of minors as a class:*

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**3.3: Condition 3: Any consent given to the research is in line with public policy**

*Consent given by authorised representatives and where applicable the minor, must be in line with public policy considerations. Describe how consent to the study will be in line with public policy, that is, explain why consent would be acceptable as the study, for example, poses acceptable risks and promotes the rights of minors:*

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**3.4: Condition 4: The research does not pose a significant risk to minors; and if there is some risk, the benefit of the research outweighs the risk.**

*Describe how the potential risks from the research procedures and/or intervention will be minimized and describe any possible benefits from the study:*

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