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INHOUD

IMPORTANT ANNOUNCEMENT

Closing times **PRIOR TO PUBLIC HOLIDAYS** *for*

GOVERNMENT NOTICES, GENERAL NOTICES, REGULATION NOTICES AND PROCLAMATIONS 2014

*The closing time is **15:00** sharp on the following days:*

- **18 September,** Thursday, for the issue of Friday **26 September 2014**
- **11 December,** Thursday, for the issue of Friday **19 December 2014**
- **15 December,** Monday, for the issue of Wednesday **24 December 2014**
- **19 December,** Friday, for the issue of Friday **2 January 2015**

Late notices will be published in the subsequent issue, if under special circumstances, a late notice is accepted, a double tariff will be charged

The copy for a SEPARATE *Government Gazette* must be handed in not later than three calendar weeks before date of publication

BELANGRIKE AANKONDIGING

Sluitingstye **VOOR VAKANSIEDAE** *vir*

GOEWERMENTS-, ALGEMENE- & REGULASIE-KENNISGEWINGS ASOOK PROKLAMASIES 2014

*Die sluitingstyd is stiptelik **15:00** op die volgende dae:*

- **18 September,** Donderdag, vir die uitgawe van Vrydag **26 September 2014**
- **11 Desember,** Donderdag, vir die uitgawe van Vrydag **19 Desember 2014**
- **15 Desember,** Maandag, vir die uitgawe van Woensdag **24 Desember 2014**
- **19 Desember,** Vrydag, vir die uitgawe van Vrydag **2 Januarie 2015**

Laat kennisgewings sal in die daaropvolgende uitgawe geplaas word. Indien 'n laat kennisgewing wel, onder spesiale omstandighede, aanvaar word, sal 'n dubbeltarief gehef word

Wanneer 'n APARTE *Staatskoerant* verlang word moet die kopie drie kalenderweke voor publikasie ingedien word

GOVERNMENT NOTICE
GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 719 **19 September 2014**

NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)
REGULATIONS RELATING TO RESEARCH WITH HUMAN PARTICIPANTS

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.

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 the Act, shall bear 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, emotional and social welfare;

"**condition**" means physical and psycho-social characteristics understood to affect health;

"**Council**" means the National Health Research Ethics Council established under Section 72 of the Act;

"**health research ethics committee**" means any committee registered in terms of Section 73 of the Act;

"**human participant**" means a living person about whom a researcher 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 Substances Act, 1965 (Act No. 101 of 1965) or its successor in title;

"**minimal risk**" means the probability and magnitude of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life in a stable society or in routine medical, dental, educational 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;

"**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 at increased risk of research-related harm, or who are limited in their freedom to make choices, or relatively incapable of protecting their own interests.

Principles guiding research with human participants

2. Health research that involves human participants must–

(a) comply with the Department of Health national ethical guidelines for research with human participants at a minimum;

(b) be responsive to health needs or priorities of the population, participating community or proposed participants;

(c) have a valid scientific methodology and be likely to provide answers for the specific research questions that are posed;

(d) include a favourable risk-benefit analysis;

(e) ensure that the recruitment and selection process is just and fair;

(f) be undertaken with appropriate consent processes;

(g) undergo independent review by a registered health research ethics committee;

(h) respect participants' rights, including but not limited to rights to dignity, privacy, bodily integrity and equality;

(i) make provision for compensation for research-related injury, for more than minimal risk research; and

(j) be managed by a lead researcher, or person with similar standing or title, with suitable experience and qualifications.

Obligations of researchers who conduct research with human participants

3. A researcher who conducts health research involving human participants must—

(a) submit the research proposal for ethics review and approval to a registered health research ethics committee and, where applicable, to the Medicines Control Council or any other body required by law, before commencing with the research;

(b) consult with representatives from the participating community or other relevant research stakeholders, where appropriate;

(c) consult with and notify the affected institutional or governmental authorities where necessary;

(d) assess the ongoing welfare of participants and take appropriate steps in the event that participants experience harms;

(e) 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; and

(f) register the research in the South African National Clinical Trials Register, if classified as a clinical trial.

Research with human participants who are vulnerable

4. Research with vulnerable persons must —

(a) involve vulnerable persons only when non-vulnerable persons are not appropriate for inclusion;

(b) not systematically avoid inclusion of vulnerable participants because to do so is unfairly discriminatory and vulnerable persons are potential beneficiaries of relevant research;

(c) be responsive to the health needs and the priorities of vulnerable persons; and

(d) receive special attention in ethical review to ensure that research-related risks are assessed and minimized and that appropriate consent procedures are followed.

4.1 Research with minors should only take place when –

(a) adults are not appropriate participants for the research;

(b) the research poses no more than a minimal risk to the minor; or

(c) the research poses more than a minimal risk, but holds out the prospect of direct benefit to the minor; or

(d) the research poses a minor increase over minimal risk, and holds out no prospect of direct benefit to the minor, but is anticipated to yield generalizable knowledge about the condition under study.

4.2 Research with adults with decision-making incapacity is appropriate when –

(a) the research cannot be conducted with adults who have decision-making capacity;

(b) the research poses no more than a minimal risk; or

(c) the research poses more than a minimal risk, but holds out the prospect of direct benefit to the participant; or

(d) the research poses a minor increase over minimal risk, and holds out no prospect of direct benefit but is anticipated to yield generalizable knowledge about the condition under study.

4.3 Research with prisoners is appropriate when –

(a) the risk of harm posed by the research is commensurate with risks that would be accepted by non-prisoner volunteers;

(b) the rights of prisoners, including but not limited to the rights to dignity, privacy, bodily integrity and equality, will be protected; and

(c) the procedures and guidelines issued by the Department of Correctional Services will be followed.

4.4 Research with persons in dependent or hierarchical relationships -

(a) includes but is not limited to research with users and their health-care workers; persons with life-threatening diseases and their care-givers, wards of the state and their guardians or care-givers, employees and their employers, prisoners and the relevant prison authorities and members of the national defence force and their superiors; and

(b) is appropriate when research-related risks of harm are minimized, and appropriate consent procedures have been followed.

Informed Consent for research with human participants

5. Human participants, or their legally authorised representatives, must be informed of –

(a) the purpose of the research;

(b) the methods and procedures, including possible randomisation;

(c) alternatives to participation in the research;

(d) the potential harms and risks of harm posed by the research;

(e) the expected benefits of the research;

(f) the freedom to choose to participate or not, or to withdraw from the research without penalty or reason;

(g) the extent to which confidentiality and privacy will be maintained;

(h) details of the contact person in the event of a query or research-related injury;

(i) reimbursement and/or incentives given for participation;

(j) information about the sponsor;

(k) any potential conflict of interests;

(l) information about approval from the health research ethics committee or the Medicines Control Council, where relevant;

(m) insurance in the event of research-related injury, for more than minimal risk research; and

(n) the availability of beneficial products or interventions post-research.

Review of proposals for research with human participants

6. All health research proposals involving human participants must–

(a) be reviewed by a health research ethics committee which is registered with the Council;

(b) satisfy the requirements as set out in the Department of Health's national ethical guidelines for research with human participants at a minimum and any additional standards as determined by the health research ethics committee; and

(c) adhere to the decisions made by the health research ethics committee.

Ministerial consent for non-therapeutic research with minors

7. Protocols for human participants' research that propose non-therapeutic research with minors must have ministerial consent in terms of Section 71(3)(a)(ii) of the Act or, where appropriate, consent from a delegated authority in terms of Section 92(a) of the Act.

(a) Applications for ministerial consent must be made on Form A;

(b) the application should be considered by the Minister or the delegated authority after the protocol is reviewed by a registered health research

ethics committee to assess whether it meets the required norms and standards of the health research ethics committee;

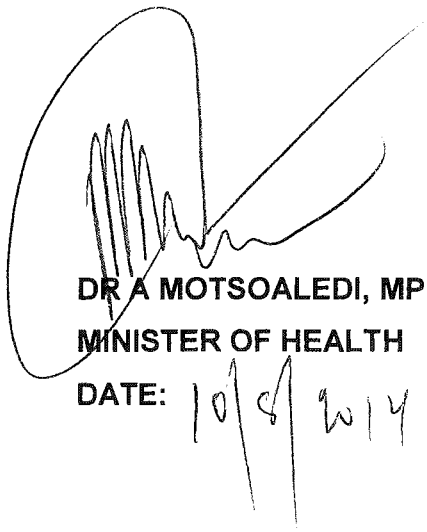
(c) in granting ministerial consent, relevant bodies or experts may be consulted;

(d) the researcher must be notified of the outcome in writing within 60 days; and

(e) the researcher may appeal the outcome including by approaching the National Health Research Ethics Council in terms of Section 72 (6) (d) of the Act.

Commencement of Regulations

8. These Regulations shall come into operation on the date of publication.



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 10/8/2014

ANNEXURES

FORM A

DEPARTMENT OF HEALTH

APPLICATION FOR MINISTERIAL CONSENT FOR NON-THERAPEUTIC RESEARCH WITH MINORS

1 INSTRUCTIONS

1.1 This application form must 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 participants 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 Section17 of the Children's Act, 2005 (Act No. 38 of 2005).

1.2 This application form should be submitted with a copy of the protocol and supporting documents.

1.3 This application should be submitted to the Minister of Health or the delegated authority in terms of Section 92(a) of the Act.

1.4 This application form should describe how 'non-therapeutic' research protocols with minors meet the conditions set out in Section 71 (3)(b) of the Act (described below).

1.5 All sections of the form must be completed in full.

1.6 Ministerial Consent may be granted for non-therapeutic health research with minors when certain conditions set out in Section 71 (3)(b) of the Act are met and these conditions are:

(a) The research objectives cannot be achieved except by the enrolment of minors;

(b) The research is likely to lead to an improved scientific understanding of conditions, or disorders affecting children;

(c) Any consent given to the research must be in line with public policy; and

(d) The research does not pose a significant risk to minors, and if there is some risk, the benefit of the research outweighs the risk.

2. INVESTIGATORS' DETAILS

Name of principal investigator	
Title of research protocol	
Institutional affiliation	
Postal Address	
Physical Address	
Email Address	
Phone	
Fax	
Date of Application	
Signature of 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. Explain why this research must be done with minors as participants:

_____
_____
_____
_____
_____
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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 might, or aims to, advance knowledge affecting the health and welfare of minors as a class. Note that 'condition' is defined in the Regulations as 'physical and psycho-social characteristics understood to affect health' allowing that this research does not only involve children with an illness.

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_____

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

Consent given by authorised persons must be in line with public policy considerations. Describe how consent to the research will be in line with public policy or would be acceptable, for example, show how the research 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 to minor participants will be minimized and describe any possible benefits from the research to society in the form of knowledge:

_____
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