

 <p>health Department: Health REPUBLIC OF SOUTH AFRICA</p>	<p>NATIONAL HEALTH RESEARCH ETHICS COUNCIL</p>	
<p>Private Bag X828, PRETORIA, 0001, Cnr Struben and Thabo Sehume Street Tel: +27 (0) 12 395 8124/8113 Fax: +27 (0) 12 395 9249</p>		

MINISTERIAL CONSENT
FOR NON-THERAPEUTIC HEALTH RESEARCH WITH MINORS:
OPERATIONAL GUIDELINES
2015

1 PURPOSE

To provide guidance to health Research Ethics Committees (RECs) and health researchers regarding Ministerial Consent for 'non-therapeutic' health research with minors.

2 BACKGROUND

1. Section 71(3)(a)(ii) of the National Health Act (NHA) requires the Minister of Health to consent to 'non-therapeutic' health research with minors, after considering whether four criteria are met (see Appendix 1).
2. The Minister may delegate authority, in terms of s 92(a), to any person in the employ of the state, a council, board or committee established in terms of the Act to give this consent.
3. The Minister has delegated authority to provide Ministerial Consent for 'non-therapeutic' health research with minors to RECs who have been found to be compliant with the audit and have achieved full registration with the NHREC. Correspondence in this regard was sent to relevant RECs on 14 October 2014. As further RECs become fully registered, their authority to exercise the delegated power will be communicated by the NHREC through the Secretariat.

4. Regulations for research with human participants, published on 19 September 2014 (R 719)(see Appendix 2), contain Form A that sets out the four criteria to be met for the additional review of 'non-therapeutic' health research with minors. Proper use of Form A should provide adequate evidence that these reviews are performed appropriately by RECs(see Appendix 3).

3 RECOMMENDATIONS FOR RESEARCHERS

1. Researchers should consider carefully whether their planned research involving minors holds out the prospect of direct benefit to participants ('therapeutic' research); or whether it holds out no prospect of direct benefit to participants but holds out the prospect of generalizable knowledge ('non-therapeutic' research).
2. Researchers conducting 'non-therapeutic' research with minors must attach Form A to the application for ethics approval.
3. The content supplied in Form A should draw on relevant sections of the protocol or ethics application, for example, the sections that deal with the scientific justification for enrolling minors; how knowledge will be advanced by enrolling minors; the benefits to society in terms of knowledge gained by enrolling minors; and the potential risks to enrolled minors and risk minimization.
4. Whether Ministerial Consent for 'non-therapeutic' health research with minors has been granted will be communicated, as part of the overall feedback about the application from the REC.

4 RECOMMENDATIONS FOR REGISTERED RECS

1. RECs with delegated authority to grant Ministerial Consent must draw to the attention of researchers the following requirements:
 - a. That researchers must consider carefully whether their planned research involving minors holds out the prospect of direct benefit to participants ('therapeutic research'); or whether it holds out no prospect of direct benefit to participants but holds out the prospect of generalizable knowledge ('non-therapeutic research').
 - b. That 'non-therapeutic' research must meet four criteria to be eligible for Ministerial Consent.

- c. That the ethics application for 'non-therapeutic' health research with minors must include Form A completed appropriately.
 - d. That where the REC judges that the research involves 'non-therapeutic' health research with minors, this view will be communicated to the researcher with a request to complete Form A accordingly.
 - e. That the content supplied in Form A should draw on relevant sections of the protocol or ethics application, for example, the sections that deal with the scientific justification for enrolling minors; how knowledge will be advanced by enrolling minors; the benefits to society in terms of knowledge gained by enrolling minors; and the potential risks to enrolled minors and risk minimization.
 - f. That the outcome (whether consent for non-therapeutic health research with minors is granted) will be communicated by the REC, as part of the overall feedback about the application.
 - g. That 'therapeutic' health research with minors does not require this additional review but is reviewed in the usual way to ensure norms and standards are met.
2. RECs should only grant Ministerial Consent after review of the application leads to the decision to grant ethics approval, and the careful review of Form A satisfies the REC that the four criteria are met.
 3. RECs should maintain specific records of such applications, and outcomes, for reporting purposes. A traceable link to each application must be maintained.
 4. RECs may devise Standard Operating Procedures (SOPs) to integrate the additional review into the overall ethics review process to facilitate efficient use of time.

5 **RECOMMENDATIONS FOR NON-REGISTERED RECs**

1. Two types of REC might not be registered with the NHREC.
2. The first type is an REC that reviews health research but has not been granted delegated authority because it is not (yet) fully registered with the NHREC. RECs that fall into this category are urged to complete the registration process as soon as possible.
3. The second type is an REC that does not review 'health research' with human subjects and is – because of the remit of its review and oversight authority – not registered and

is unlikely to seek registration. While such RECs are not required to address the issue of Ministerial Consent, they should carefully review non-health research including the justification for the involvement of minors.

6 CONCLUSIONS

1. It is hoped that the delegation of authority from the Minister to fully registered RECs to grant Ministerial Consent for 'non-therapeutic' research with children will resolve an important issue in the short-term, while appropriate law reform of section 71 is pursued in the medium term.
2. RECs and researchers are requested to send feedback to the NHREC about the process of granting Ministerial Consent and the adequacy of these operational guidelines, so that improvements can be made.

Appendix 1: CURRENT WORDING: S 71 OF THE NATIONAL HEALTH ACT

Research on or experimentation with human subjects

(1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-

(a) in the prescribed manner; and

(b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.

(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-

(a) if it is in the best interests of the minor;

(b) in such manner and on such conditions as may be prescribed;

(c) with the consent of the parent or guardian of the child; and

(d) if the minor is capable of understanding, with the consent of the minor.

(3) (a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted-

(i) in such manner and on such conditions as may be prescribed;

(ii) with the consent of the Minister;

(iii) with the consent of the parent or guardian of the minor; and

(iv) if the minor is capable of understanding, the consent of the minor.

(b) The Minister may not give consent in circumstances where-

(i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;

(ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;

(iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;

(iv) the research or experimentation poses a significant risk to the health of the minor; or

(v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

Appendix 2: CURRENT WORDING: S 7 OF THE REGULATIONS FOR RESEARCH WITH HUMANN PARTICIPANTS

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.

Appendix 3: FORM A AS PUBLISHED IN THE REGULATIONS FOR RESEARCH WITH HUMAN PARTICIPANTS

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 section 17 of the Children’s 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:

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.

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:

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: