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. 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).
   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. 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).
  2. All sections of the form must be completed in full.
  3. 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:

1. The research objectives cannot be achieved except by the enrolment of minors;
2. The research is likely to lead to an improved scientific understanding of conditions, or disorders affecting children;
3. Any consent given to the research must be in line with public policy; and
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 assessment.

# 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 |  |

## APPLICATION

* 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:
  1. **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.
  1. **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:
  1. **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: