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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 4.4 RESEARCH INVOLVING MINORS

Approved by:	Name	Signature	Date
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COMPILED BY Dr Janet Hayward, Chair, Rhodes University Human Research Ethics Committee

DOCUMENT HISTORY

Version 1.01 (November 2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference and Standard Operation Procedures).

Version 2.0 (April 2024): Derived from division of previous version into separate documents and revised to align with RU Research Policy (2021) and DoH Guidelines (2015; 2024).

RESEARCH INVOLVING MINORS

1. Purpose

The purpose of these guidelines is to outline the special considerations that need to be made when conducting research with children as participants.

2. Research activities involving children

2.1. Children below the age of eighteen (minors) have limited capacity to choose independently whether to participate in research.

2.2. A parent or guardian must assist their child in making this choice. In doing so, the parent or guardian does not choose for the child whether or not they should participate but must give permission for the minor to make the choice themselves.

2.3. Children under the age of 12 years old should participate in research only where their participation is indispensable to the research and where participation is not contrary to the individual child's best interests. The ethics application must provide sufficient information to justify clearly why children under 12 years should be included as participants.

2.4. Research activities involving a child under and over 12 years should be approved only if:

1) the activity, including observational research, places the child at no more than minimal risk
2) the activity involves more than minimal risk but provides possible benefit for the child participant. In this case, the degree of risk must be justified by the potential benefit.
3) the activity, including observational research, involves greater than minimal risk, with no prospect of direct benefit to the child participant, but has a high probability of providing significantly generalisable knowledge: the risk needs to be justified by the risk-knowledge ratio.

2.5. Consent for children to participate in research must be obtained from:

1) the child, where the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the research
2) the parents or legal guardian, and
3) any organisation or person required by law (if applicable).

2.6. The researcher must ensure adequate steps to obtain the child's informed assent when the child is capable of providing such assent. The application must document whether and how such assent shall be given.

2.7. A child's refusal to participate must be respected.

3. Parental permission

3.1. Where the research does not involve greater than minimal risk to the child or involves greater than minimal risk but presents the likelihood of direct benefit to the child, the permission of one parent is sufficient.

3.2. Permission from both parents is necessary where the research involves greater than minimal risk, is of no direct benefit to the child but is likely to produce generalisable knowledge.

3.3. Where only one parent is available for reasons including the death, incompetence or disappearance of the other, or where a court has placed the child in the sole care and contact of one parent, then the permission of that one parent is sufficient for participation in the latter type of research.

3.4. In the event of conflicting views between the parents, the child's best interest settles the matter, as agreed upon by the Human Research Ethics Committee in discussion with the researcher.

3.5. Unmarried mothers who are under the age of 18 years may not consent to the participation of their children in research investigations. Their guardians (usually their parents) are also the guardians of her child and must thus consent to the child's participation as set out above.

4. Categorisation of risk levels in research with children

4.1. Studies with children are not automatically medium- or high- risk:

4.2. As defined in the Rhodes University Research Ethics Policy: Research with Human Participants, (p 8) "usual classroom, educational or psycho-social activities may include minors; where minors are not expected to do anything more than participate in usual activities associated with these activities, the study may be assigned low risk status." For a study to involve medium risk, the participants – including children – need to be exposed to greater risks than those "imposed by daily life under stable social conditions."

5. Waiver of the requirement of written parental permission [1]

5.1. The South African's Children's Act [No. 38 of 2005] states that minors may consent to medical treatment without parental permission, if they are "of sufficient maturity and have the mental capacity to understand the benefits, risks, social and other implications of the treatment".

5.2. Similarly, in particular circumstances, it may be desirable and ethically justifiable for minors (especially older minors i.e., 16 years and older) to choose independently (without parental assistance) whether to participate in research.

5.3. Examples would include sensitive issues such as sexual activity, substance use and abuse, etc. Reasons supporting the desirability of independent consent may include recruiting enough minors who would be unwilling to participate if they had to tell their parents about the nature of the research to obtain parental permission.

5.4. The researcher must make an ethical justification for independent consent by minors.

5.5. The researcher should engage with relevant role players, for example a representative body of parents and provide factual evidence of such engagement, such as a letter confirming that independent consent is acceptable.

5.6. RU-HREC may grant a waiver of the requirement of written parental permission if the committee accepts the ethical justification and the factual evidence of parental support for independent choice by their minor children.

5.7. The process must be carefully documented.

[1] DoH Guidelines, 2015:26)

6. Effective date of this SOP

29 April 2024 with the next revision date being 29 April 2027, or as deemed necessary by a quorate meeting of Rhodes University Human Research Ethics Committee.