University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR RESEARCH INVOLVING MINORS

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. PURPOSE OF THE SOP

The purpose of this SOP is to describe the general and specific ethical, regulatory and legal requirements for conducting research with children and adolescents.

3. SCOPE

The scope of this document covers the responsibilities and procedures when conducting research with children and adolescents.

4. RESPONSIBILITIES

The UFH HREC must determine whether the risks to minors are sufficiently minimised, informed consent and assent are appropriate, and privacy and confidentiality protections are adequate.

5. PROCEDURE(S)

5.1 Definition of terms

'**Adolescent**' means a child between the ages of 12 and 17 years of age (ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 [http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf]

'**Caregiver**' means a person who factually cares for a child (section 1 Children's Act, 38 of 2005; a caregiver is obliged (in terms of section 32(1)) to safeguard the child's health, well-being and development; and to protect the child from abuse and other harms. Further, a caregiver may exercise the parental right to consent to medical examination or treatment of the child (in terms of section 32(2)

'**Child**' means a person under the age of 18 years (section 28 Constitution; section 1 Children's Act 38 of 2005)

'**Child-headed household**' means a household per section 137 Children's Act 38 of 2005

'**Guardian**' means a person appointed by a court to look after the financial and welfare interests of a minor, or a person appointed by a parent with sole responsibility for the minor in terms of the parent's Will

'**Harm**' means physical, emotional, psychological, social or legal harm

'**Minor**' means a person (child) less than 18 years (section 17 Children's Act 38 of 2005)

'**Neonate**' means a newborn child, including an infant less than a month old

'**Orphan**' means a child who has no surviving parent caring for him or her (section 1 Children's Act 38 of 2005)

'**Parent**' includes an adoptive parent (s 1 Children's Act 38 of 2005)

'**Therapeutic research**' means research that includes interventions that may hold out the prospect of direct health-related benefit for the participant (Regulation 135)

'**Non-therapeutic research**' means research that includes interventions that will not hold out the prospect of direct health-related benefit for the participant but may produce results that contribute to generalisable knowledge (Regulation 135)

5.2 Minimum conditions for research involving minors

Reviewing research involving child and adolescent participants must include members with appropriate paediatric research experience. The following considerations are critical when the UFH HREC reviews proposals to involve child and adolescent participants:

a) Children should participate in research when their participation is scientifically indispensable. The research should investigate a problem of relevance to children. The protocol should provide sufficient information to *justify clearly, the inclusion of children as participants*.

b) Children should participate in research only where such research poses acceptable risks of harm. That is, research involving minors should be approved only if:

- The research, including observational research, is not contrary to the best interest of the minor; the following are among the criteria which must be considered when determining a child's 'best interests':
    - age, maturity and stage of development
    - background
    - the child's intellectual, emotional, social and cultural development
    - any disability a child may have
    - any chronic illness from which a child may suffer

- The research, including observational research, places the minor at no more than minimal risk of harm (i.e. the 'everyday risks standard' which means the risk of harm is equal with daily life in a stable society or routine medical, dental, educational or psychological tests or examinations; or

- The research involves greater than minimal risk of harm but provides the prospect of direct benefit for the minor. The potential benefit should justify the degree of risk of harm; or
- The research, including observational research, involves greater than minimal risk of harm, with no prospect of direct benefit to the minor, but has a high probability of providing significant generalisable knowledge. The risk-knowledge ratio should justify the degree of risk of harm.

- Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.

  Where appropriate, the minor will assent to participate.

c) The UFH HREC will evaluate the degree of risk of harm against the likelihood of benefit to the child participant as outlined in b) above.

d) Children should participate in research only where the proper written permissions have been obtained. The consent process for a minor's participation in research requires
   - Permission in writing from parents or legal guardian for the minor to be approached and invited to participate (in accordance with section 10 of the Children's Act 38 of 2005);
   - Assent from the minor in writing (i.e. agreement to participate) if they choose to participate.

e) Children's privacy interests should be addressed.

f) The minor's interest in confidentiality, i.e. being identified or identifiable without permission of the minor **and** her parent or guardian must be respected.

g) Research involving children must respect their evolving capacity to give consent.

h) Researchers have a legal obligation to report child abuse and neglect. They should report under the following:

Children's Act 38 of 2005 (as amended by Act 41 of 2007)

- Physical abuse causing injury
- Deliberate neglect
- Sexual abuse including sexual offences.

The Criminal Law (Sexual Offences and Related Matters) Amendment Act No.32 of 2007

- Rape and sexual assault
- Statutory rape and sexual assault
- Consensual sexual penetration or other sexual activity

5.3 Parental permission and substitutes

Parents or guardians may not decide whether their minor child should participate in research without the minor's contribution to the decision. The process should request the parent or guardian to allow the minor to be approached and invited to participate in the study. The parental permission and the minor's decision must be consistent.

The parental substitutes should be used in descending order, as listed.

a. The minor chooses whether to participate and thus expresses her will **AFTER**
b. The parent assists with understanding (so the minor makes an informed choice)
c. If no parent, then guardian: either court-appointed OR as indicated by the parent in Will (section 27 Children's Act)
d. If no guardian, then foster parent (per order of Children's Court) (Note that social workers should request that the authority to give permission should be included expressly in the court order authorising foster care).
e. If no foster parent (per iv. above), then caregiver (s 1 Children's Act: defined as '…any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care centre where a child has been placed; e) the person at the head of a shelter; f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and g) the child at the head of a child- headed household').
f. If a minor is a caregiver in a child-headed household and has no supervisory adult (section 137 Children's Act), then a trusted adult nominated by the minor, including but not limited to the social worker, community worker or teacher.

5.4 Minors' independent consent

In certain conditions, e.g. for reasons of sensitivity, like the discussion about sexual activities, substance abuse etc., it may be necessary and ethically justified for minors (especially older minors, i.e. 16 years and older) to choose independently, i.e. without parental assistance, whether to participate in research. Generally, only minimal risk research is suitable for independent consent by minors.

An ethical justification for independent consent by minors may be made in the following manner:

- By prior engagement with participating community role players, the researcher can request (and justify explicitly) UFH HREC approval of a waiver of the parental (or substitute) permission requirement. Engagement could include outreach to relevant role players such as canvassing the opinion of a representative body of parents, e.g. via schools.
- Factual evidence of such engagement must form part of the researchers' justification in the protocol. Factual evidence may be a letter from a relevant role player (like a community leader, or school principal) confirming that independent consent is acceptable to the parents.
- Supposing the UFH HREC finds the ethical justification and, factual evidence of parental support for independent choice by their minor children acceptable, the UFH HREC may grant a waiver of written parental permission and document the process carefully.

5.5 Guidelines for drafting an assent form

'Assent is an interactive process between a researcher and child participant involving disclosure of cognitively and emotionally appropriate information regarding, at minimum, why the child is being asked to participate, a description of the procedures and how the child might experience them, and an understanding that participation in the study is voluntary. Children should understand that they can decline participation or withdraw from the study at any time. Assent requires that the child explicitly affirm his or her agreement to participate in a manner that reflects their age-appropriate understanding and is free of undue influence or coercion. In the absence of an explicit agreement, the mere failure of the child to object cannot be construed as assent.

The document should be limited to one page for younger children if possible. Illustrations might be helpful, and a larger font type makes a form easier for young children to read. Studies involving older children or adolescents could include more information and use more complex language.

Researchers should try to draft a form that is:

- Brief;
- Contains simplistic language written at the appropriate age level;
- Study specific;
- Considers the typical child's experience;
- Treats the child respectfully;
- Conveys the essential information about the study.

The assent form should:

- Tell why the research is being conducted;
- Describe what will happen and for how long or how often;
- Say that it is up to the child to participate and that it is okay to say no;
- Say what the child's other choices are;
- Describe any good things that might happen;
- Say whether there is any compensation for participating; and
- Ask for questions.

6. REFERENCE DOCUMENTS

The UFH HREC adopts as its guiding reference the following documents:

- Children's Act 38 of 2005 (as amended by Act 41 of 2007)
- Constitution of the Republic of South Africa, 1996
- Sexual Offences and Related Matters Amendment Act No.32 of 2007
- ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 [http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf]
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).
- University of South Africa, SOP for minors

[1] Trait, A.R & Geisser, M. E. 2017. Development of a consensus operational definition of child assent for research. *BMC Medical Ethics*, 18:41. https://doi.org/10.1186/s12910-017-0199-4