

Using the concept of 'parental responsibilities and rights' to identify adults able to provide proxy consent to child research in South Africa

Ann Elaine Strode, BA, LLB, LLM

Faculty of Law, University of KwaZulu-Natal, Durban

Catherine May Slack, BA, BA Hons, MA (Clinical Psychology)

HIV/AIDS Vaccines Ethics Group, University of KwaZulu-Natal

Corresponding author: A E Strode (strodea@ukzn.ac.za)

There are circumstances where independent consent to research by children is appropriate (for example, where the participants are older adolescents and the research approximates minimal risk). However, in many instances an important safeguard will be a dual consenting process involving an appropriate adult alongside the potential child participant (according to their evolving capacities). But what adults are appropriate in what instances? We attempt to use principles set out in the Children's Act (2010) to address this question. This article differentiates between those adults who according to the Children's Act (2010) have full parental responsibilities and rights (i.e. parents/guardians) and those who have no parental responsibilities and rights (i.e. caregivers). We argue that some responsibilities accorded to caregivers are substantially similar to the authority to provide proxy consent to research in which the research risks approximate those risks present in the child's everyday life. In these instances, we argue that where parents and guardians are not available, caregivers should be considered by research ethics committees as a possible source of proxy consent for younger children. This approach might not be logically extended to caregiver consent for clinical trial enrolment, for which alternative arguments may need to be debated.

In South African law, consent must be given by a person who is legally capable of consenting.¹ Juristic acts are dependent on the expression of the will of the parties and therefore only those who possess a reasonable understanding and judgment have the capacity to act.² The capacity of children to participate in legal transactions is generally limited to protect them from their lack of intellectual or cognitive ability, inexperience and social or emotional immaturity.² Despite this general principle, it is recognised by the law that children have evolving capacity which develops with age. Accordingly, children are able to consent independently to a range of **health-related interventions** before adulthood, such as HIV testing (at 12 years) and male circumcision (at 16 years) (Children's Act, 2005).³ Where children do not have legal capacity to consent independently, the Children's Act allows children to be assisted by appropriate adults, not limited to parents and legal guardians.² This includes in some circumstances those holding no parental responsibilities and rights towards the child such as caregivers (s 18 and s 32(1)).³

Although the law recognises the evolving capacity of children with regard to various health interventions, the current legal framework for **health research** is more conservative. Section 71 of the National Health Act (No. 61 of 2003) does not allow children to consent independently to any form of health research. It also limits the ability to provide proxy consent to parents and legal guardians. Although passed by parliament in 2003 notice has never been issued of the date on which this section of the Act will be *implemented*. Accordingly, as the provisions on research with children in the National Health Act are not in operation and there is no other law establishing when children may consent to research most research ethics committees (RECs) rely on the principles

in ethical guidelines. Some of these allow children to consent independently to research in certain circumstances and recognise a broader range of adults eligible to provide proxy consent in some instances.⁴ This inconsistent approach across the Children's Act, the National Health Act and ethical guidelines regarding a child's evolving capacity (and the adults with authority to provide proxy consent) has led to implementation complexities.³ This article focuses on the issue of proxy consent to health research. It argues that the concept of parental responsibilities and rights within the Children's Act can assist research stakeholders to clarify this issue.

Legal framework for parental responsibilities and rights

With the implementation of the Children's Act (2005)⁵ South African law moved from a narrow focus on biological parents to the concept of 'parental responsibilities and rights'. These are obligations owed by certain persons towards a child, including, caring for the child, maintaining contact, acting as a guardian and providing maintenance (s 18).⁵ The Children's Act⁵ also recognises the role played by persons who have no parental rights and responsibilities in respect of a child. These are persons who voluntarily provide day-to-day care for children and the Act describes the nature of the obligations on such persons to care and protect the child (s 32(1)).⁵ To explore whether 'parental responsibilities and rights' can be used to identify persons who can provide proxy consent for child research participation we must, firstly, define parental responsibilities and rights, and secondly, identify persons with and without such obligations.

Article

Defining parental responsibilities and rights

Persons who care for children may have: (i) full or partial parental responsibilities and rights in respect of a child (s 18(1)) or (ii) no parental responsibilities and rights (s 32).⁵

Full parental responsibilities and rights include: firstly, a duty to care for the child; secondly, an obligation to maintain contact with the child; thirdly, a duty to act as guardian of the child; and fourthly, a duty to contribute to the maintenance of the child (s 18(2)).⁵ There are some highly significant decisions which can only be made by persons with full parental responsibilities and rights. These include: consent to a child's marriage, adoption, departure or removal from the Republic, application for a passport, and the alienation or encumbrance of any immovable property belonging to the child (s 18(3)).⁵

A court may award **partial** parental responsibilities and rights to an interested party such as a grandparent when the person with full responsibilities is prepared to share these rights and obligations (s 22, 23 and 24).⁵ Partial parental responsibilities and rights are not defined in the Act. In such a case the nature of the shared responsibilities would be determined by agreement between the parties or a court order.

Persons with **no** partial responsibilities and rights but who provide day-to-day care for the child are required to *safeguard the child's health, well-being and development and protect the child from harm* (s 32(1)) (italics ours).⁵ Section 129(4) of the Children's Act also specifically provides that 'caregivers' may provide consent for a child's medical treatment and HIV testing (s 130(2)(b)).⁵ Persons with no parental responsibilities and rights may exercise any parental responsibilities or rights that may be necessary to ensure that the child's well-being is maintained and he/she is protected from harm (s 32(2)).⁵

Identifying persons with parental responsibilities and rights for a child

The biological mother, the biological father (in certain circumstances) and a child's legal guardian all have full parental responsibilities and rights for a child, while a caregiver who is not a biological parent or legal guardian has no parental responsibilities and rights.

The Children's Act provides that generally parents or legal guardians of the child have full parental responsibilities and rights. The biological mother of a child will be the child's legal guardian unless she is under the age of 18 and unmarried at the time of the child's birth (s 19).⁵ Where the biological mother is under the age of 18, is unmarried and the father of the child does not have parental responsibilities and rights as discussed below, then her guardian (the maternal grandmother) is also the child's guardian until the biological mother reaches the age of 18 (s 19(2)).⁵ If the mother marries before the age of 18 she becomes the child's guardian at this point.² **Accordingly, a biological mother, as the child's legal guardian, has the authority to consent to all forms of health research on behalf of the child as long as she is 18 years or older, or under the age of 18 and married.**

The biological father of a child is not automatically the legal guardian of the child and therefore does not always have parental responsibilities and rights. If the father is over 18 years of age or was married to the biological mother at any point during her pregnancy or after the birth of the child, then he is the joint guardian

of the child and has this authority (s 20).⁵ If he is not and has never been married to the mother, then he will only have parental responsibilities and rights under the following circumstances: at the time of the child's birth, he was living with the mother in a permanent life partnership; or he has consented to being identified as the child's father; or he has paid damages in terms of customary law; or he has contributed to or attempted to contribute towards the child's up-bringing and expenses. If any of these situations exist, the biological father will have full parental responsibilities and rights with the biological mother (s 21). **Accordingly, biological fathers do not always have parental responsibilities and rights, but when they do, they can consent on behalf of the child to all forms of health research.**

Other than the biological parents, there are a number of persons who may acquire **full** or partial parental responsibilities and rights. This may be done in a number of ways. Firstly, the biological mother of a child or any other person who has parental responsibilities and rights may enter into an agreement with another person in terms of which such a person acquires parental responsibilities and rights for a child (s 22(1)).⁵ Secondly, guardianship may be assigned to any person by an order of the High Court (s 24(1)).⁵ Thirdly, a person who is the sole guardian of a child may, through a will, nominate another person to act as the child's guardian on their death (s 27(1) and (2)).⁵ Fourthly, parental responsibilities and rights may be conferred by an adoption order (s 242(2)).⁵ **Accordingly, a person who has acquired full parental responsibilities and rights can consent on behalf of the child to all forms of health research.**

The Children's Act provides that where more than one person has parental responsibilities and rights in respect of a child, they are both competent to exercise these obligations independently and without the consent of the other (s 18(4)).⁵ This means, for example, that only one parent would need to provide consent to health research (unless otherwise specified by ethical guidelines) and would not be required to consult with the other guardian. Nevertheless, in 'major decisions' which could affect, among other things, the child's health, the person making the decision must give due consideration to firstly, the views of the child in the light of their 'age, maturity and stage of development' (s 31(1)(a)), and secondly, 'any co-holder of parental responsibilities and rights in respect of the child' (s 31(2)(a)).⁵

In our law, persons who are not biological parents and have no parental responsibilities and rights are nevertheless accorded a number of responsibilities. This is most often the case for caregivers (persons who are not a parent or guardian but factually care for a child), such as a foster parent, a person who cares for a child with the implied or express consent of a parent or guardian, a person who cares for a child while the child is temporarily in safe care, the person at the head of a child and youth-care centre where the child has been placed, the person in charge of a shelter, a child and youth-care worker who cares for a child that does not have appropriate family care in the community, and the child at the head of a child-headed household (where the child is 16 years or older) (s 1).⁵ We will argue below that even though caregivers are accorded no parental responsibilities and rights in our law, caregivers are the bearers of a number of duties that logically correspond with the nature of decision making relating to proxy consent to certain forms of health research, and therefore, caregivers (with some exceptions) should have the authority to provide proxy consent to certain forms of health research.

Caregiver duties include an obligation to protect the child's health and to consent to their medical treatment or HIV testing. Table I summarises the types of persons who have full parental responsibilities and rights for a child and those without, according to the Children's Act 2005.⁵

Applying parental responsibilities and rights to consent for research

In preparing the first draft of the Children's Act,⁵ the South African Law Reform Commission took cognisance of the restrictive approach in the old Child Care Act No. 74 of 1983 which made obtaining proxy consent for treatment with children difficult if they were not living with parents or guardians. The Commission found that this had a negative impact on providing health services to children. To facilitate access to treatment for children, the Commission recommended that caregivers be given the authority to provide such consent.⁶ Recent research has confirmed that 26% of South African children live with caregivers and of this group 80% of the caregivers were grandparents or relatives.⁷ This approach was adopted by parliament in crafting s 129(4) of the Children's Act⁵ which allows consent for medical treatment to be provided by, among others, a parent, a guardian or a caregiver. Against this background we argue that placing duties on persons without parental responsibilities and rights to protect the health of children in the Children's Act is a significant legal innovation as it enables such persons to perform functions such as consenting to medical treatment which in turn promotes a child's health and well-being.

Research involving minimal risk or a minor increase over minimal risk

We submit that where proxy consent is necessary for research, consent from persons with *no parental* responsibilities and rights but who provide day-to-day care of children, namely caregivers, ought to be permissible where the research approximates minimal risk (and other requirements are met).

Some research involves minimal risk or a minor increment over minimal risk. Minimal risk is anchored to risks encountered in daily life or during routine medical or psychological examinations.⁸ A minor increase over minimal risk is linked to risks commensurate with those in a child's medical, dental, psychological, social or educational setting.⁹ The functions of persons who take day-to-day care of a child include an obligation to safeguard the child's health, well-being and development and to protect children from 'maltreatment, abuse, neglect, degradation, discrimination, exploitation, and any other physical, emotional or mental harm or hazards' (s 32(1), Children's Act, 2010). They are also charged with consenting to medical treatment (s 129(4)) and HIV testing (s 130(2)(b)).

We assert that in many instances decisions regarding children's participation in minimal risk research would approximate decisions regarding children's day-to-day care. Therefore, caregivers ought to be able to consent to minimal risk research. For example, we argue that caregivers could consent to studies into the social protection needs of orphans and vulnerable children, or studies that examine the time young children spend playing with 'electronic toys' per week.

We accept that there will be complexities associated with allowing caregivers to consent to minimal risk research. A parent or guardian may exist who wishes to be involved in decisions affecting the child, and bypassing such persons with no effort to contact them may result in conflict. There may also be conflicts regarding how to establish when a parent or legal guardian is not reasonably available. Some caregivers (such as the heads of child-headed households who are under the age of 18) may be too vulnerable to be given the responsibility of providing proxy consent to research. Furthermore other caregivers (such as heads of children's shelters) may be targeted to consent to the research participation of children under their care (although the selection of children for non-scientific and convenience purposes would be rejected by most RECs on justice grounds).¹⁰ Nevertheless we do not believe these complexities outweigh the advantages of adopting the approach taken towards parental

Table I. Persons with parental responsibilities and rights according to the Children's Act (2005)

Persons with FULL parental responsibilities and rights

- Biological mothers who are 18 years or older
- The maternal mother, where the biological mother is under the age of 18
- Biological fathers who are married to the biological mother
- Biological fathers, over the age of 18, who have lived with or are living with the child's mother in a permanent life partnership
- Biological fathers who have acknowledged by particular actions that the child is their child
- Adoptive parents
- Persons who have been assigned such rights by the biological mother or a High Court order
- Persons who have been appointed in a will as the guardian of a child

Persons with NO parental responsibilities and rights

Caregivers including:

- Grandmothers
- Aunts/uncles
- Foster parents
- The head of a child-headed household who is over the age of 16

responsibilities and rights in the Children's Act⁵ because RECs could refuse to allow specific caregivers to act as proxies.

In general, we recommend that the following conditions ought to be attached to caregiver consent for research:

1. The risks of the research should be minimal or represent a minor increase over minimal risk;
2. It should be established that the children themselves cannot consent independently, for example, in the case of older adolescents;⁸
3. No person with full parental responsibilities and rights in respect of the child should be available to provide consent, or they are not reasonably available;
4. The adult from whom consent is sought ought to be a caregiver as defined in the Children's Act. It should be established whether the heads of child-headed households should be excluded even though they are classified as caregivers in terms of the Children's Act; and
5. Where possible, written notice should be sent to the person with full parental responsibilities and rights, informing them of the child's involvement in the minimal risk study and the obtaining of proxy consent from a caregiver.

Research involving increased risk

Based on the principles explored in this paper, it appears less logical that caregiver consent be extended to clinical trial enrolment. Although current clinical trial guidelines⁹ allow such consent where parents or guardians are not readily available, decisions about participation in clinical trials cannot be as easily equated with decisions about day-to-day care of children. This is because of the potentially higher risks involved in, and the exceptional nature of, clinical trials. The Children's Act 2005⁵ has excluded caregivers from making some highly exceptional decisions, such as granting permission for a child to marry. Is enrolment into a clinical trial another example of an exceptional activity? We suggest that more debate is needed around this issue, and that alternative arguments may need to be put forward regarding the circumstances in which caregiver consent for clinical trial enrolment would be acceptable.

Table II illustrates the way in which we propose these principles could be implemented.

Risk	Consent	Example
Research where the risks are minimal or a minor increase over minimal	Older child: consent unassisted	Survey of experiences in receiving treatment for sexually transmitted infections
	Younger child: consent from caregiver if parent unavailable	Survey of perceptions of school counselling services
Research where the risks represent more than a minor increase over minimal	Any child: consent from a parent or guardian	Clinical trial

Conclusion

In some instances, children should provide independent consent to health research, e.g. older adolescents participating in minimal risk research.⁸ In other instances, proxy consent is an important protection. We argue that where parents or guardians do not exist or are not reasonably available, and the research approximates minimal risk, then persons who provide day-to-day care of children even if they have no parental responsibilities and rights in respect of the child (i.e. caregivers) should be allowed to provide consent for such research, with the caveats outlined above. We argue that this would not only facilitate research with children but it would act as an important protection for them.

Implications for ethical guidelines

Current general ethical guidelines state that consent for children to participate in health research must be obtained from the parents or legal guardian. However, where the research is minimal risk and no community objection is anticipated, older children may consent to research unassisted.⁸ These guidelines should be amended to include a 'middle ground' between parental consent on the one hand, and independent consent on the other hand, namely caregiver consent for minimal risk research for younger children. More specifically, it is submitted that the terminology of the Children's Act should be used, and persons with the legal authority to consent on behalf of the child to medical treatment should be recognised as being able to give proxy consent to certain forms of research.

Current clinical trial guidelines⁹ require parental or guardianship consent, failing which a caregiver providing long-term care for the child may provide proxy consent. On this specific analysis, caregiver consent should not be extended to clinical trials; however, we submit that further debate is required on this issue in order to establish those circumstances in which caregivers could give consent for enrolment into clinical trials.

Acknowledgements and disclaimer. This research was funded by the South African AIDS Vaccine Initiative (SAAVI). The views represented here are not necessarily the views of SAAVI. Thanks are due to an anonymous reviewer for an insightful review of the paper.

Article

References

1. Van Oosten F. The law and ethics of information and consent in medical research. *THRHR* 2000;63(1):5-30.
 2. Heaton J. *The South African Law of Persons*. Durban: Lexis Nexis Butterworths, 2009.
 3. Strode A, Slack C, Essack Z. Child consent in South African law: implications for researchers, service providers and policy makers. *S Afr Med J* 2010;100:247-249.
 4. Strode A, Slack C, Mushariwa M. HIV vaccine research: South Africa's ethical-legal framework and its ability to promote the welfare of trial participants. *S Afr Med J* 2005;95(8):598-601.
 5. Children's Act No. 38 of 2005.
 6. Report on the Review of the Child Care Act, No. 74 of 1983. South African Law Reform Commission, 2002.
 7. *South Africa's Children: A Review of Equity and Child Rights*. Department of Women, Children and people with Disabilities, South African Human Rights Commission and UNICEF, 2011.
 8. Department of Health. *Ethics in Health Research: Principles, Structures and Processes*. Pretoria: DOH, 2004.
 9. Department of Health. *Guidelines for good practice in the conduct of clinical trials with human participants in South Africa*. 2006: <http://www.doh.gov.za/docs/index.html> (accessed 5 March 2008).
 10. Emanuel E, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis* 2004;189:930-937.
-