

THE LAW ABOUT MEDICAL RESEARCH ON MINORS AND CONSENT REQUIREMENTS: TIME TO HARMONISE THE LAW?

By

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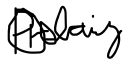
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DECLARATION

I declare that this report is my own, unaided work. It is submitted in partial fulfilment of the requirements for the degree of Master of Laws in the field of Information and Communications at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any other degree or examination in any other university.

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ABSTRACT

The existing South African legal framework, especially the National Health Act 61 of 2003 ('NHA'), governs the requirements for children to consent to participate in medical research. However, the NHA undermines the consent of a child to participate in medical research without parental consent, which will be explored. The Constitution of South Africa, the Children's Act, and the Choice on Termination of Pregnancy Act must also be considered when determining consent requirements for children involved in medical research. The Children's Act adopts a more flexible approach to consent requirements for medical treatment and acknowledges a child's evolving maturity. Should this be extended to the NHA?

The NHA fails to address the evolving autonomy of children. Furthermore, it does not adequately consider sensitive research involving adolescents, such as issues related to sexual and reproductive health. The NHA definition of medical research is also too comprehensive and needs to be categorised to address when parental consent is required, if at all. It is crucial to compare various legislation to the NHA when exploring consent requirements for minors. The incongruencies in our legislation suggest an amendment to the NHA is necessary to align with the Children's Act and other legislation involving minors and international law. Moreover, the applicability of the POPIA raises a debate among academics about consent requirements for medical research. The POPIA should clarify whether it applies to health research in light of other sectoral legislation that explicitly regulates medical research.

Therefore, there is a need to harmonise the current legal framework to allow adolescents to consent to participate in medical research, without parental consent, especially considering their evolving autonomy. Harmonising our legislation is essential to advance medical research and improve healthcare for children in South Africa.

TABLE OF CONTENTS

DECLARATION.....	2
ABSTRACT	3
1. INTRODUCTION.....	5
2. THE CONSTITUTION OF SOUTH AFRICA AND INFORMED CONSENT.....	6
3. THE UNITED NATIONS CONVENTION ON THE RIGHTS OF THE CHILD...7	
4. THE CHILDREN'S ACT AND CONSENT.....	8
5. THE CHOICE ON TERMINATION OF PREGNANCY ACT, 92 OF 1996.....	12
6. THE NATIONAL HEALTH ACT AND MINOR CONSENT.....	13
(a) The 2014 Regulations relating to research with Human Participants.....	17
(b) The 2015 Department of Health Guidelines on Ethics in Health Research.....	18
(c) The 2024 Department of Health Guidelines on Ethics in Health Research.....	20
7. EVALUATION OF THE CURRENT LAWS DEALING WITH CONSENT AND MINOR CHILDREN RELATING TO MEDICAL RESEARCH.....	21
(a) The consent for a minor is limited to parents and guardians.....	21
(b) The evolving capacities of minors and adolescents.....	22
8. THE POPIA AND CONSENT REQUIREMENTS.....	25
(a) The public interest.....	26
(b) Section 3(2)(a) of the POPIA	28
9. INTERNATIONAL HEALTH RESEARCH INVOLVING ADOLESCENTS....	30
10. CONCLUSION AND RECOMMENDATIONS FOR SOUTH AFRICAN LAW	32
11. BIBLIOGRAPHY.....	34

1. INTRODUCTION

South African legislation requires a consistent approach to obtaining consent from minors involved in medical research. Legislation relating to children and medical research will be explored to assess the necessary criteria for obtaining lawful consent to participate in medical research. This is fundamental to ensuring ethical and legal compliance by researchers in medical research involving children.

It is indisputable that children, as a vulnerable group within our society, deserve extra protection.¹ For this reason, children in South Africa are prohibited from performing legal acts without the consent of their parent or legal guardian, except under certain circumstances.² This legal measure aims to protect children from their lack of judgment owing to their 'immaturity'.³ However, our laws have positively shifted over time to allow children to consent to certain juristic acts themselves, enabled by the Constitution of the Republic of South Africa, 1996 ('the Constitution') and the Children's Act 38 of 2005 ('the Children's Act').⁴ Although the Children's Act does not directly address medical research, it deals with medical intervention involving children, and children's rights.

Additionally, the Choice on Termination of Pregnancy Act 92 of 1996 ('the Choice Act') provides guidance for determining the factors for a child's legal capacity to consent to medical procedures. Therefore, the existing laws can be used for evaluating whether a child can consent independently to participate in medical research.

Most importantly, the National Health Act 61 of 2003 ('NHA'), its Regulations and the Ethics Guidelines specifically deal with minors and medical research and will be examined. Lastly, the Protection of Personal Information Act 4 of 2013 ('the POPIA') will also be considered to determine whether it influences the requirements for obtaining consent when conducting medical research on children.

¹ Donnelly, D.L. and Thaldar, D. W. 'Children as participants in health research in South Africa: A response to Labuschaigne, Mahomed and Dhai' (2023) *Developing World Bioethics* 1–5 at 1.

² Kruger H 'The Protection of Children's Right to Self-Determination in South African Law with Specific Reference to Medical Treatment and Operations' (2018) 21 *PER / PELJ* 1-34 at 2.

³ Ibid.

⁴ Ibid at 3.

A medical practitioner treating a patient for a medical condition differs significantly from a researcher conducting medical research.⁵ The role of the researcher is to develop and advance medical knowledge, health education, medicines and procedures for the benefit of society, and the most accurate way to do so is to use human participants, including children, in the research and trials.⁶ Therefore, South Africa has stringent consent laws to protect children from perceived and genuine dangers that could arise while participating in medical research.⁷

The legislature is challenged to balance children's autonomy and the need to empower children to make decisions on matters relevant to them with the need to protect them from harm and promote their rights.⁸ Moreover, legislating laws for children relating 'to the stages of "childhood"', which encompasses many transitional phases for a child, creates additional challenges for the legislature, for laws relating to adolescence.⁹ Our current laws should clarify the criteria for when it is appropriate for children, specifically adolescents, to consent autonomously without parental or guardian permission to participate in medical research. The lack of consistency in our law involving children in medical intervention compared with medical research creates discord and should be reformed. Harmonisation is thus required to address this lacuna.

2. THE CONSTITUTION OF SOUTH AFRICA AND INFORMED CONSENT

The Constitution directly impacts a child's capacity to consent to specific actions because it recognises children as autonomous beings with independent rights.¹⁰ Therefore, it will guide the type of consent required for a child to consent to medical research.

The Constitution expressly acknowledges the necessity of medical research. This is supported by the Constitution directing that 'everyone has the right to bodily and psychological integrity, which includes the right... not to be subjected to medical or

⁵ E B Worku, A M Davis, B M Morrow 'A critical review of health research ethical guidelines regarding caregiver consent for HIV research involving minors in South Africa: Ethical and legal issues' (2016) 9(2) *S Afr J Bioethics Law* 78-83 at 78.

⁶ Ibid.

⁷ Ibid.

⁸ Moritz, Dominique and Mathews, Ben 'A Continuum of Protection to Empowerment: The Evolving Legal Landscape of Decision-Making for Children and Adolescents' (2023)12(89) *Laws* at 2.

⁹ Ibid.

¹⁰ Kruger op cit note 2 at 3.

scientific experiments without their informed consent'.¹¹ Further, the Constitution protects individuals against being treated in 'cruel, inhuman or degrading' ways.¹² Accordingly, obtaining informed consent is a prerequisite for researchers and highlights the importance of autonomy in our law when conducting medical research. Therefore, the opportunity to provide 'informed consent' to medical intervention is a constitutional right.¹³ From this, the question arises of how far this constitutional right extends to children to provide informed consent themselves to participate in medical research and under what circumstances, especially as medical research is broader than only clinical trials, which are invasive.

The Constitution defines a child as someone younger than 18 years old.¹⁴ It states that 'every child has the right... to basic health care services...'.¹⁵ It also directs that 'a child's best interests are of paramount importance in every matter concerning a child'.¹⁶ Kruger opines that a view recognising 'the evolving capabilities of children who have the required level of maturity to make independent decisions' corresponds to an approach that satisfies this criteria.¹⁷ Thus, considering the Constitution, a child's best interests must be prioritised when conducting medical research, and the benefit of the research must improve children's healthcare. This stance should be incorporated when determining whether our laws are tailored to enable children to consent lawfully.

3. THE UNITED NATIONS CONVENTION ON THE RIGHTS OF THE CHILD

Considering international law, Article 12 of the United Nations Convention on the Rights of the Child ('UNCRC') conveys that children can express their opinions and participate in matters concerning them.¹⁸ Children's views must also be 'given due weight' according to their 'age and maturity' level.¹⁹ Kruger highlights the importance of reading Article 5 of the UNCRC with Article 12.²⁰ Article 5 states that parties are 'to

¹¹ Section 12(2)(c) of the Constitution.

¹² Section 12(1)(e) of the Constitution.

¹³ Njotini MN 'Preserving the Integrity of Medical-Related Information – How 'Informed' is Consent?' (2018) 21 *PER / PELJ* 1-20 at 4.

¹⁴ Section 28(3) of the Constitution.

¹⁵ Section 28(1)(c) of the Constitution.

¹⁶ Section 28(2) of the Constitution.

¹⁷ Kruger op cit note 2 at 19.

¹⁸ Article 12(1) UNCRC.

¹⁹ Article 12(1) UNCRC.

²⁰ Kruger op cit note 2 at 15.

respect the responsibilities, rights and duties of parents or... legal guardians ... to provide, in a manner consistent with the evolving capacities of the child, appropriate direction and guidance in the exercise by the child of the rights'. Article 5 acknowledges that children's abilities develop and that guidance provided by parents or guardians should correspond with their developmental stage appropriately.²¹ This infers that mature children have the right to make decisions independently without requiring parental consent in certain matters.²²

Accordingly, the autonomy of children must be a factor when considering consent requirements and determining whether our laws regarding medical research are insufficient compared to international child law.

4. THE CHILDREN'S ACT AND CONSENT

Examining the Children's Act when dealing with medical matters concerning children is crucial. In terms of the Children's Act, a 'child' is defined as 'a person under the age of 18 years'.²³ Labuschaigne *et al* submit that although the Children's Act does not explicitly regulate a minor's consent to research, it permits a minor to independently consent to other significant decisions, such as access to contraceptives, virginity testing, HIV testing and circumcision.²⁴ Therefore, despite the act's shortfall in dealing with medical research, since the Children's Act deals with other health-related issues, it can also assist when it is appropriate for a child to decide when to consent to medical research independently.²⁵

Section 7 of the Children's Act sets out factors to consider what is in 'the best interests of the child'.²⁶ While the Children's Act does not expressly define what is in 'the best interests of the child', in medical research, these factors assist in determining when a child can consent to participate in medical research.²⁷ Namely, the child's age,

²¹ Ibid.

²² Ibid.

²³ Chapter 1 section 1 definition of "child" in the Children's Act.

²⁴ Labuschaigne, M., Mahomed, S. & Dhali, A. 'Evolving capacity of children and their best interests in the context of health research in South Africa: An ethico-legal position' (2022) *Developing World Bioethics* 1–9 at 8.

²⁵ Ibid.

²⁶ Section 7 of the Children's Act.

²⁷ Labuschaigne *et al* op cit note 24 at 5.

maturity, stage of development,²⁸ gender,²⁹ background,³⁰ and any other relevant characteristics.³¹ Further, section 7 of the Children's Act conveys the necessity for the law to safeguard children 'from any physical or psychological harm caused by...maltreatment, abuse, neglect, exploitation or degradation'.³² Therefore, a medical practitioner must consider these subjective factors to protect a child's physical and mental well-being.³³ Similarly, these factors must be considered when conducting medical research on children.

Moreover, section 9 of the Children's Act reiterates that 'in *all matters* concerning the care, protection and well-being of a child the standard that the child's best interest is of paramount importance, must be applied' (my emphasis). Labuschaigne *et al* point out that section 9 of the Children's Act reaffirms section 28(2) of the Constitution.³⁴ Thus, the meaning of *all matters* can be interpreted to extend to medical research.

Very importantly, section 10 of the Children's Act states that 'every child that is of such an age, maturity and stage of development as to be able to participate in any matter concerning that child has the right to participate appropriately and views expressed by the child must be given due consideration'.³⁵ Moyo suggests that this provision incorporates Article 12 of the UNCRC to comply with international obligations.³⁶ In this manner, it can be understood that the Children's Act would permit a child, where appropriate, to partake in medical research if they chose to do so.

However, Moritz and Matthews explain that even when children are allowed to express their views and participate in decision-making, they are still not autonomous, as this only occurs when they can consent themselves, irrespective of their parents' or guardians' views.³⁷ Ultimately, the parent or guardian may still be required to consent on behalf of the child to be regarded as lawful consent.³⁸ Even when a child has the

²⁸ Section 7(1)(g)(i) of the Children's Act.

²⁹ Ibid section 7(1)(g)(ii).

³⁰ Ibid section 7(1)(g)(iii).

³¹ Ibid section 7(1)(g)(iv).

³² Ibid section 7(1)(i).

³³ Labuschaigne *et al* op cit note 24 at 5.

³⁴ Ibid.

³⁵ Section 10 of the Children's Act.

³⁶ Admark Moyo 'Child participation under South African law: Beyond the convention on the rights of the child?' (2015) 31(1) SAJHR at 174.

³⁷ Moritz and Mathews op cit note 8 at 4.

³⁸ Ibid at 5.

mental capacity to make an informed decision, the law fails to grant children 'agency' in many appropriate circumstances, such as participation in medical research.³⁹

To elaborate on the relevance of the Children's Act to medical research, Section 129 of the Children's Act provides guidance regarding a child's informed consent to medical interventions. Section 129(2) provides that 'a child may consent to his or her medical treatment or the medical treatment of their child if the child is over the age of 12 years old and the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment'.⁴⁰ However, to test a child's maturity is subjective.⁴¹ No specific test has been formulated to objectively measure when a child is mature enough to make decisions autonomously.⁴² Ganya *et al* further point out that the Children's Act fails to define 'medical treatment' and suggests that medical research could be included as medical treatment as medical treatments vary, and so does medical research.⁴³ In this regard, perhaps medical research could be regarded as medical treatment, whereby the age to consent to medical research could be 12, should the child be mature.

Section 129(3) of the Children's Act states that a child may consent to the performance of a surgical operation on them if the child is over the age of 12 years; and the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation; and the child is *duly assisted* by his or her parent or guardian.⁴⁴ Mahery points out that 'parental assistance' is required instead of 'consent'.⁴⁵ Mahery cautions that this may create challenges when interpreting the meaning of 'assistance' and what our law requires.⁴⁶ The author argues that while lawful consent is defined in our law, it is ambiguous as to when 'assistance' is lawful.⁴⁷ Pillay and Singh add that the word 'duly' indicates that parents

³⁹ Ibid at 4.

⁴⁰ The Children's Act section 129(2)(a) and (b).

⁴¹ Kruger op cite note 2 at 22.

⁴² Ganya, W., Kling, S. & Moodley, K. 'Autonomy of the child in the South African context: is a 12 year old of sufficient maturity to consent to medical treatment?' (2016) (17)66 *BMC Medical Ethics* at 3.

⁴³ Ibid at 2.

⁴⁴ The Children's Act section 129(3)(a), (b) and (c).

⁴⁵ P Mahery 'Consent laws influencing children's access to health care services' (2006) *SAHR* 167–180 at 169.

⁴⁶ Ibid.

⁴⁷ Ibid.

or guardians assisting their children should do so meaningfully and sincerely to form an ultimate decision about the medical matter with their child.⁴⁸

The Children's Act does not specify a particular age when a child matures. Instead, it provides that in section 129(4)(b), a parent can consent on behalf of a child, even though the child is over the age of 12, where the 'child...is of insufficient maturity or is unable to understand the benefits, risks and social implications of the treatment'. Therefore, although a child may be over 12, they cannot provide lawful consent in some instances to medical treatment. Similarly, this would apply to medical research, especially if there is a risk of harm to the child.

The Children's Act respects the 'evolving autonomy' of older children in matters relating to their healthcare while simultaneously emphasising the importance of their understanding and informed consent.⁴⁹ To support this notion, Van Heerden *et al* conducted research that concluded that children over 12 can make health-related decisions.⁵⁰ Similarly, this age should be considered when determining consent requirements for children to participate in medical research.

Conversely, there are also concerns relating to the notion of a child's evolving capabilities. Assessing a child's maturity level and mental capacity is a challenge.⁵¹ Namely, South African law fails to define 'sufficient maturity', 'mental capacity' or 'capacity to understand'.⁵² There are no defined guidelines in the Children's Act or its regulations that help clarify what is required when performing a test to measure maturity and mental capacity.⁵³ Additionally, any test performed by the healthcare practitioner is 'time-consuming' and healthcare practitioners may not be suitably qualified to perform the test.⁵⁴ Therefore, it is vital that medical practitioners receive suitable training on assessing a child's maturity level to protect a child's right to self-

⁴⁸ Basil J Pillay and Jerome A Singh 'Mental capacity', 'sufficient maturity', and 'capable of understanding' in relation to children: how should health professionals interpret these terms?' (2018) 48(4) *South African Journal of Psychology* 538–552 at 540.

⁴⁹ Moyo op cit note 36 at 181.

⁵⁰ J van Heerden, R Delpont, M Kruger 'Children's ability to consent to medical management in South Africa' (2020) 14(1) *S Afr J Child Health* 25-29 at 28.

⁵¹ Y Havenga and MA Temane 'Consent by children: considerations when assessing maturity and mental capacity' (2016) 58(1) *South African Family Practice* 43-46 at 43.

⁵² Pillay and Singh op cit note 48 at 539.

⁵³ Havenga and Temane op cit note 51 at 43.

⁵⁴ *Ibid*.

determination.⁵⁵ In the same regard, any medical researcher must scrutinise a child's maturity when considering the consent criteria to participate in medical research.

5. THE CHOICE ON TERMINATION OF PREGNANCY ACT 92 OF 1996 ('Choice Act')

The Choice Act is an exception where a minor can consent to a medical or surgical procedure, irrespective of age.⁵⁶ This is illustrated in the definition of a 'woman', who is 'any female person of any age'.⁵⁷ Therefore, this would include a female minor. A pregnant woman, during the first 12 weeks of her pregnancy,⁵⁸ can provide informed consent for the termination of her pregnancy,⁵⁹ with the only consent required being that of the pregnant woman.⁶⁰ Consequently, a girl would not require the consent of her parents or guardian to proceed with the abortion.

While research involving minors is not dealt with in the Choice Act, the act allows children to independently consent to abortions.⁶¹ Further, the Choice Act does not require any proof to demonstrate a minor's level of maturity or mental capacity to comprehend the risks and implications of the procedure required to terminate the pregnancy.⁶² The Choice Act eliminates all 'parental responsibility' to consent on behalf of their daughter to have an abortion on the premise that she is sufficiently competent to decide to terminate the pregnancy on her own.⁶³ Moyo cautions that there is 'no logical' connection between actually falling pregnant and the 'competence' of a child to have adequate maturity to decide whether or not to terminate her pregnancy.⁶⁴ One would also need to consider the individual circumstances under which the child fell pregnant in the first place, such as a child having been raped as opposed to consensual sex. Therefore, potential risks for the child are possible as medical practitioners could lawfully grant 'autonomy' to a child who is incapable of

⁵⁵ Kruger op cit note 2 at 26.

⁵⁶ Labuschaigne *et al* op cit note 24 at 7.

⁵⁷ Section 1(xi) of the Choice Act.

⁵⁸ Section 2(1)(a) of the Choice Act.

⁵⁹ Section 5(1) of the Choice Act.

⁶⁰ Section 5(2) of the Choice Act.

⁶¹ Labuschaigne *et al* op cit note 24 at 7.

⁶² *Ibid.*

⁶³ Moyo op cit note 36 at 183.

⁶⁴ *Ibid.*

making independent medical decisions and should acquire parental assistance to make an informed decision.⁶⁵ While advocating for children's rights is encouraged, it is crucial to prevent any unintended harm to a child.

In this regard, the Choice Act far exceeds a child's 'autonomy levels' as envisaged in Article 12 of the UNCRC and the Children's Act.⁶⁶ Strode *et al* suggest that compulsory counselling and additional support for girls under the age of 14 terminating their pregnancy must be legislated.⁶⁷ This suggests that there needs to be a balanced approach between giving a child too much autonomy, which could result in harm to a child and the necessity of parental intervention to guide their child. Similarly, when evaluating the appropriateness of a child to consent to medical research, the potential harm to children must be factored in, requiring parental consent, for example, drug testing.

6. THE NATIONAL HEALTH ACT AND MINOR CONSENT

The NHA is crucial to examine when it comes to consent and medical research involving minors. It requires that a participant provide informed consent.⁶⁸ For informed consent to be present, the 'health care provider' must notify the patient of 'the benefits, risks, costs and consequences' in connection with the medical intervention.⁶⁹ Moreover, practitioners must inform even competent child patients about their corresponding right to refuse treatment.⁷⁰ Therefore, just as one has the right to participate in medical research, one can also rightfully refuse to participate. However, the scope to which a minor has the potential opportunity to consent to participate in research is extensive.

At the outset, section 1 of the NHA defines "health research" to include '*any research which contributes to knowledge of-*

⁶⁵ Ibid.

⁶⁶ Ibid at 184.

⁶⁷ A E Strode, Z Essack, C M Slack 'Adolescent self-consent to medical interventions in South Africa' (2023) 17(3) *S Afr J Child Health* 136 at 138.

⁶⁸ Section 7(1) of the NHA.

⁶⁹ Section 6(1)(c) of the NHA.

⁷⁰ Section 6(1)(d) of NHA – definition of 'user' in section 1.

- (a) the biological, clinical, psychological or social processes in human beings;*
- (b) improved methods for the provision of health services;*
- (c) human pathology;*
- (d) the causes of disease;*
- (e) the effects of the environment on the human body;*
- (f) the development or new application of pharmaceuticals, medicines and related substances;*
- (g) the development of new applications of health technology’.*⁷¹

The definition is significant because it illustrates that medical research is wide-ranging and broader than merely clinical trials, which can be invasive to the participant. Mathews explains that the ‘nature’ of the research and the surrounding environment where the research occurs would assist in determining the level of parental consent required, such as observational research, which has minimal risk.⁷² Based on this notion, ‘health research’ in the NHA is defined too broadly. It requires categorisation of the subsections relating to what types of parental consent are required in specific circumstances, such as when the research is invasive or observational. This will determine when parental consent is required. The definition should demarcate what kind of consent is required and under what circumstances, such as questionnaires, interview-based research, observational research or clinical trials involving drugs. Mathews considers that adolescents can autonomously consent to participate in ‘health-related research based on lived experiences’ and, in certain instances, clinical trials, owing to the low risk that may be presented.⁷³ This, for example, could correlate to (b) in the definition of the NHA of medical research, where a questionnaire could be filled out to ascertain what is required for better access to healthcare for adolescents. It is also argued that simple health questionnaires, for example, on depression, where the risk to children is exceptionally minimal, would not even be classified as medical research in terms of the NHA, which Mathews may agree with.

⁷¹ Section 1 Definitions of the NHA.

⁷² Mathews, B ‘Adolescent Capacity to Consent to Participate in Research: A Review and Analysis Informed by Law, Human Rights, Ethics, and Developmental Science’ (2023) 12(2) *Laws* at 6.

⁷³ *Ibid* at 3

Legislation and research ethics guidelines are drafted with biomedical research in mind where there is a risk of harm to the person participating in the research or the prospect of participation in the research is involuntary.⁷⁴ This is supported by medical research ethics guidelines founded on principles established in the Nuremberg Code (1947) and the Declaration of Helsinki, where medical research involves human experiments.⁷⁵ This is apparent in the NHA, which regulates medical research under the heading ‘the research on or experimentation with human subjects’.⁷⁶ Saying that, this could apply to only (f) and (g) in the definition of ‘health research’ in the NHA, where the consent of a parent or legal guardian would undoubtedly be required.

Research on children in South Africa is primarily regulated by sections 71(2) and (3) of the NHA.⁷⁷ In terms of section 71 of the NHA, children under 18 cannot autonomously consent to participate in medical research at all.⁷⁸ These provisions mandate that research can only be conducted with the informed consent of a ‘parent or guardian’ and with the assent of the minor ‘where the minor is capable of understanding’.⁷⁹ Accordingly, even if the child is sufficiently mature to consent independently, permission from a parent or guardian is still required.⁸⁰

Contrary to the Children’s Act, the NHA does not differentiate children into ‘age categories, but rather, considers children to be one group and categorises the research outcomes into “therapeutic” and “non-therapeutic research”’.⁸¹ Regarding ‘therapeutic’ research, it may only be conducted ‘if it is in the best interests of the minor’,⁸² and ‘with the consent of the parent or guardian of the child’,⁸³ and ‘if the minor is capable of understanding, with the consent of the minor’.⁸⁴

⁷⁴ Ibid at 26.

⁷⁵ Ibid.

⁷⁶ Section 71 of the NHA.

⁷⁷ Strode, Ann Elaine and Slack, Catherine May ‘Child research in South Africa: How do the new regulations help?’ (2015) 105(11) *S Afr Med J* 899-900 at 899.

⁷⁸ A Strode, M Richter, M Wallace, J Toohey, K Technau ‘Failing the vulnerable: Three new consent norms that will undermine health research with children’ (2014) 15(2) *S Afr J HIV Med* 46-49 at 47.

⁷⁹ E B Worku, A M Davis, B M Morrow op cit note 5 at 79; Sections 71(2)(c) and (d) of the NHA.

⁸⁰ Ibid at 79.

⁸¹ Section 71(2) and (3) of the NHA; The Health Professions Council of South Africa: Guidelines for Good Practice in The Health Care Professions ‘General Ethical Guidelines for Biotechnology Research in South Africa’ (Booklet 14) at para 2.6.4.4.2. at 17.

⁸² Section 71(2)(a) of the NHA.

⁸³ Section 71(2)(c) of the NHA.

⁸⁴ Section 71(2)(d) of the NHA.

When conducting 'non-therapeutic' research on a minor, it can only proceed 'with the consent of the Minister',⁸⁵ 'with the consent of the parent or guardian of the minor',⁸⁶ and 'if the minor is capable of understanding, the consent of the minor'.⁸⁷ The function of the Minister has subsequently been delegated to the Research Ethics Committees ('RECs').⁸⁸ The National Health Research Ethics Council ('NHREC') has drafted guidelines for the RECs and medical researchers regarding ministerial consent for 'non-therapeutic' health research for children.⁸⁹ In this regard, RECs that have successfully complied with audits and have fully registered with the NHREC can provide Ministerial Consent for 'non-therapeutic' health research with minors.⁹⁰ Therefore, a REC can only provide consent under certain strict conditions.

Chapter 9 of the NHA establishes the 'system' of RECs to oversee all medical research in South Africa.⁹¹ Therefore, any institution that intends to conduct medical research must have 'its own' REC, or must 'have access to' a REC that is registered with the NHREC.⁹²

The RECs may not provide consent for the research to proceed where the purpose of the research can be achieved if it is conducted on an adult rather than a child; the research is unlikely to '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'; the research 'is contrary to public policy'; and there is a health risk to the minor if the research is conducted, which harm does not sufficiently outweigh the benefit of the risk.⁹³ Labuschaigne *et al* point out that while section 71(2) mandates consideration of a child's 'best interests' in approving therapeutic research, no such requirement exists for non-therapeutic research.⁹⁴ This requirement should also be extended to non-therapeutic research to better protect a child's rights.

⁸⁵ Section 71(3)(a)(ii) of the NHA.

⁸⁶ Section 71(3)(a)(iii) of the NHA.

⁸⁷ Section 71(3)(a)(iv) of the NHA.

⁸⁸ Pillay and Singh op cit note 48 at 540.

⁸⁹ National Health Research Ethics Council (NHREC): Ministerial Consent For Non-Therapeutic Health Research With Minors: Operational Guidelines (2015) at para 1 'Purpose'.

⁹⁰ Ibid at para 3.

⁹¹ Thaldar DW and Townsend BA 'Exempting Health Research from the Consent Provisions of POPIA' (2021) (24)(1) *PER / PELJ* 1 – 31 at 4; Sections 69-73 of the NHA.

⁹² Ibid; Section 73(1) of the NHA.

⁹³ Section 71(3)(b)(i - v) of the NHA.

⁹⁴ Labuschaigne *et al* op cit note 24 at 6.

The NHA prescribes that in addition to parental consent, a child can only participate if the child is 'capable of understanding', which places an extra onus on the researcher to determine if the child is adequately mature and, if so, to obtain the child's consent.⁹⁵ Therefore, in non-therapeutic research, the burden echoes the Children's Act challenges relating to the evolving capabilities of children as to when they would be able to have the maturity to consent. Labuschaigne *et al*, however, supports this additional consent requirement from the child and explains that the conjunction 'and' in sections 71(2)(d) and 71(3)(a)(iv) of the NHA signifies that this requirement is compulsory, so researchers have to abide by it.⁹⁶ Therefore, should the child be aware of the potential outcomes and understand the medical research objectives, they would also need to consent for added safeguards to their rights.⁹⁷

The NHREC provides additional guidance to researchers seeking approval from a REC regarding when parental consent can be waived.⁹⁸ This, however, contradicts the NHA because there are no exceptions available in the NHA. The regulations and guidelines relating to children and medical research will be examined. Most significant is that the NHA contrasts with these regulations and guidelines.

a) The 2014 Regulations relating to research with Human Participants

The 2014 Regulations to the NHA for 'Research with Human Participants' ('the Regulations')⁹⁹ attempted to address the standards outlined in section 71 of the NHA.¹⁰⁰ The Regulations consider children as 'participants who are vulnerable'.¹⁰¹ Classifying children as vulnerable would be in accordance with the Constitution and the Children's Act.

⁹⁵ Donnelly and Thaldar op cit note 1 at 3.

⁹⁶ Labuschaigne *et al* op cit note 24 at 6.

⁹⁷ Ibid.

⁹⁸ Conduct Of Research Involving Minors – Waiver Of Parental Consent SAMRC Human Research Ethics Committee (November 2021).
<https://www.samrc.ac.za/sites/default/files/attachments/202307/HRECguidance%20on%20parental%20waiver.docx> (accessed 26 December 2023).

⁹⁹ South African Government Regulations Relating to Research with Human Participants. Government Gazette No. R 719 of 19 September 2014.

https://www.gov.za/sites/default/files/gcis_document/201409/38000rg10268gon719.pdf

¹⁰⁰ Strode and Slack op cit note 77 at 899.

¹⁰¹ Regulation 4.1 of the South African Government Regulations Relating to Research with Human Participants.

The Regulations assist in defining the terms that are not defined in the NHA.¹⁰² Namely, Therapeutic research is research ‘that holds out the prospect of direct benefit to the participant’.¹⁰³ Non-therapeutic research is defined as ‘research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalisable knowledge’.¹⁰⁴ Therefore, the Regulations guide researchers in categorising their research protocols involving minors and provide clarity on the criteria when the consent of the Minister is required.¹⁰⁵

b) The 2015 Department of Health Guidelines on Ethics in Health Research (NDoH 2015)

While the NDoH 2015 are not applicable anymore, they are relevant for comparing it to the new current guidelines. The notion that children can only make decisions at a specific age may violate certain ‘ethical principles’, questioning the validity of consent requirements.¹⁰⁶ This is true for the NHA with a blanket age of 18 to consent to participate in medical research. According to the NDoH 2015, children could only participate in medical research when ‘proper written permissions have been obtained’.¹⁰⁷ However, in contrast to the NHA, these Guidelines recognise exceptions where minors do not have to obtain parental or guardian consent, as in the Children’s Act and Choice Act.¹⁰⁸ In the same manner, these Guidelines provided exceptions in certain circumstances where parental or guardian consent is not required for medical research, notwithstanding the child is a minor, as the RECs can waive parental or guardian consent.¹⁰⁹

These include certain instances involving ‘sexual activities’ and ‘substance abuse’, where it would be inappropriate and unjustifiable to obtain parental consent in children

¹⁰² Strode and Slack op cit note 77 at 899.

¹⁰³ Section 1, definition of “therapeutic research” - South African Government Regulations Relating to Research with Human Participants.

¹⁰⁴ Section 1, definition of “non-therapeutic research” - South African Government. Regulations Relating to Research with Human Participants.

¹⁰⁵ Strode and Slack op cit note 77 at 900.

¹⁰⁶ Moritz and Mathews op cit note 8 at 5.

¹⁰⁷ Paragraph 3.2.2.1(e) of the 2015 Ethics Guidelines.

¹⁰⁸ Paragraph 3.2.2.1(e) of the 2015 Ethics Guidelines.

¹⁰⁹ Labuschaigne *et al* op cit note 24 at 8; National Department of Health. South Africa Ethics in health research: Principles, processes and structures (2015) <https://www.health.gov.za/nhrec-home/> (accessed 3 January 2023) at 23 para 3.2.2.

over 16 years old to participate in the research where the harm to the participant is so 'minimal', and the parental consent would deter the participant in participating.¹¹⁰ In this event, 'ethical justification' to waive parental consent from the REC is obtained where there is 'prior engagement with participating community role players' and where there is 'factual evidence' reflecting such engagement, confirming that it is acceptable by the parents for the minors to consent autonomously.¹¹¹ Subsequently, should the REC accept the 'ethical justification' and the proof of 'parental support', the REC is permitted to 'grant a waiver of the requirement of written parental permission', but such process must be meticulously documented.¹¹²

While this parental waiver appears positive, it can also be criticised as arbitrary. Strode and Essack point out that these guidelines fail to define what constitutes a 'community' and which community members are qualified to provide the requisite parental waiver.¹¹³ Moreover, whether this waiver is a blanket substitution for parental consent or is simply permission from the parent for the child to consent themselves.¹¹⁴ The ambiguity surrounding the application of this waiver has led to it being applied inconsistently and requires clarity.¹¹⁵

The NDoH 2015 contrast the NHA's requirement that a parent consent for a minor to participate in research because the REC can waive this requirement, which approach causes confusion as these guidelines undermine the scope provided by law, being the NHA.¹¹⁶ Nevertheless, a nuanced approach is critical to facilitate child participation in medical research.¹¹⁷

¹¹⁰ Ibid at 26 para 3.2.2.4.

¹¹¹ Ibid.

¹¹² Ibid.

¹¹³ A E Strode and Z Essack 'Parental waivers to enable adolescent participation in certain forms of health research: lessons from a South African case study' (2022) 23(98) *BMC Medical Ethics* at 5.

¹¹⁴ Ibid.

¹¹⁵ Ibid.

¹¹⁶ Ibid at 1.

¹¹⁷ Ibid at 5.

c) The 2024 Department of Health Guidelines on Ethics in health Research (NDoH 2024)

The NHREC has subsequently issued new ethics Guidelines in accordance with section 72 of the NHA ('NDoH 2024').¹¹⁸ These Guidelines hold that a parent or guardian will still need to provide consent for a child or adolescent to participate in health research but add that the child or adolescent's consent is also required.¹¹⁹ Parental and child assent must be consistent in agreeing to the participation.¹²⁰ Accordingly, if the child wishes to participate and the parent withholds consent, the child will not be able to participate in the health research.¹²¹ This does not grant children any agency.

The NDoH 2024 guidelines repeat that in certain circumstances, it is permissible for adolescents to consent to participate in health research owing to parental waiver, where the risk to the child is minimal.¹²² These guidelines also take the approach that the 'community stakeholders' must be engaged to validate whether the waiver of consent is acceptable.¹²³ Thereafter, the researcher must be able to satisfactorily prove the engagement to the REC and furnish evidence, such as a letter from a community leader.¹²⁴ Should the REC accept the 'ethical justification' based on the evidence, the REC may waive parental consent.¹²⁵ Therefore, the NDoH 2024 does not advance the consent requirements or seek to clarify any ambiguity apparent in the NDoH 2015. This is a missed opportunity to harmonise consent requirements between the NHA and its regulations and guidelines. Moreover, it does not change the fact that the guidelines over-step the consent requirements provided for in the NHA.

¹¹⁸ National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH.

¹¹⁹ NDoH 2024 at 33 para 3.2.2.2.

¹²⁰ Ibid.

¹²¹ Ibid.

¹²² NDoH 2024 at 35 para 3.2.2.4.

¹²³ Ibid.

¹²⁴ Ibid.

¹²⁵ Ibid.

7. EVALUATION OF THE CURRENT LAWS DEALING WITH CONSENT AND MINOR CHILDREN RELATING TO MEDICAL RESEARCH

After examining the laws relating to medical research involving minors, it is necessary to address areas where the legislation may fall short and acknowledge where there is harmony in our law.

a) The consent for a minor is limited to parents and guardians

In South African legislation, informed consent of a minor must be provided by a parent (biological or adoptive) or guardian (legal authority acting on behalf of a child).¹²⁶ This has been illustrated in the legislation concerning medical intervention. However, in our developing country, there are many households where children are cared for by caregivers other than a parent or legal guardian.¹²⁷ These would include, for example, a foster parent, a child of a child-headed household, a grandmother or other relative who has been provided with the tacit consent to act as the parent or guardian.¹²⁸ In these instances, the caregiver would not be lawfully entitled to consent on behalf of the minor.¹²⁹ By permitting consent only from a parent or guardian, this definition creates adverse barriers to research.¹³⁰ It excludes caregivers from providing informed consent for the minor to participate, as the act precludes them from doing so owing to their lack of legal authority, despite their willingness to do so and even when the research would be advantageous to the child.¹³¹ This would be most important for therapeutic research, benefiting the child directly.

Tension exists between Section 71(2)(c) of the NHA and the National Ethics Guidelines concerning consent for child research.¹³² The NHA confines consent to 'parents or guardians', but the NDoH 2015 permit a 'broader range of consent' methods in certain circumstances.¹³³ These permit a caregiver to provide consent for a minor in medical research without a parent or legal guardian, which denotes a positive change to consent requirements.¹³⁴ This also acknowledges the position in

¹²⁶ Worku, Davis and Morrow op cit note 5 at 78.

¹²⁷ Ibid 79.

¹²⁸ Ibid.

¹²⁹ Ibid.

¹³⁰ Ibid.

¹³¹ Ibid.

¹³² Strobe and Slack op cit note 77 at 900.

¹³³ Ibid; Strobe and Essack op cit note 113 at 2.

¹³⁴ Worku, Davis and Morrow op cit note 5 at 80; Section 3.2.2.3 of the revised 2015 Ethics Guidelines.

South Africa where children do not necessarily live with their parents but rather a caregiver.¹³⁵

Most recently, the NDoH 2024 echoes that there is ethical justification for allowing 'parent substitutes' to consent to child participation in research in certain circumstances.¹³⁶ When the child or adolescent expresses their desire to participate in the research, and the risk is low, parental substitutes such as a foster parent, caregiver, or the child at the head of a child-headed household are permissible depending on the child's circumstances.¹³⁷ Noteworthy is that the child must first consent themselves. Therefore, the NHA is too rigid and an amendment to section 71 must include a broad definition of caregivers to provide consent for minor children.

b) The evolving capacities of minors and adolescents

The Children's Act fails to address the consent requirements for a child to participate in medical research, resulting in inconsistencies in our law.¹³⁸ It is counterproductive to permit children to autonomously acquire medical services affecting their health, yet simultaneously, the law denies them the possibility to engage in medical research, especially therapeutic research, that could enhance their health.¹³⁹

When comparing these laws, the NHA fails to recognise that children can make informed decisions themselves (without the added requirement for parental consent), as opposed to the Children's Act, where children can have a say in their medical decisions.¹⁴⁰ It is contradictory to deny minors the opportunity, without parental consent, to participate in medical research that may benefit them while being permitted to 'independently' access services that affect their general health and reproductive choices.¹⁴¹ Consequently, Labuschaigne *et al* propose that section 71 of the NHA be amended to include that children are evolving and are becoming mature enough to make decisions commensurate with their level of maturity and mental capacity and should be able to participate in research where appropriate and the risk of harm is

¹³⁵ Strode and Essack op cit note 113 at 2.

¹³⁶ NDoH 2024 at 33 para 3.2.2.2.

¹³⁷ NDoH 2024 at 34 para 3.2.2.2.

¹³⁸ Loveday M, Goga A, Dhai A, et al. 'Ethically acceptable consent approaches to adolescent research in South Africa' (2022) 23(1) *S Afr J HIV Med* at 2.

¹³⁹ *Ibid*.

¹⁴⁰ *Ibid* at 7.

¹⁴¹ Labuschaigne *et al* op cit note 24 at 7.

low.¹⁴² Therefore, the NHA is inadequate and the problem is entirely regarding the additional requirement for parental consent, which is what Labuschaigne *et al* argue. Accordingly, the Children's Act advocates for minors' active participation in choices that pertain to their well-being, but the NHA fails in this regard, especially where the risk is low. The NHA should align with the Children's Act to permit children with the requisite maturity to participate in medical research where appropriate.

The issue of adolescents, who are also regarded as children, is specifically crucial for children's evolving capacities in medical research and consent. There is no specific definition for adolescence in legislation, but it generally refers to individuals aged between 10 and 19.¹⁴³ While the notion that all adolescents are vulnerable is in line with the Constitution, is incorrect in certain circumstances because the risk of harm is so minimal in particular research on sensitive topics.¹⁴⁴ Mathews proposes that based on numerous amounts of evidence, adolescents of 16 years old are capable of consenting to participation in research.¹⁴⁵

Owing to social and economic pressures in the physical world and the online space, adolescents constantly face challenges regarding drug abuse, sexual violence and cyberbullying, which adversely impact their physical and mental health.¹⁴⁶ The NHA falls short of considering any sensitive research such as homosexuality in adolescents, teenage abortions, or children participating in illegal behaviour, such as drug or alcohol use, where parents could disapprove of their children's behaviour.¹⁴⁷ It is therefore critical to conduct research on adolescents to address their increasing problems and find solutions for them.¹⁴⁸ In this regard, section 71 of the NHA fails to consider that adolescents in South Africa are becoming more autonomous in our society and can play a pivotal role in this vital research.¹⁴⁹ This is further aggravated by the NHA's failure to provide 'exceptions' for parental or guardian consent.¹⁵⁰ Therefore, the law undermines the consent of the minor. Consequently, capable

¹⁴² Ibid at 8.

¹⁴³ Donnelly and Thaldar *op cit* note 1 at 2.

¹⁴⁴ Mathews *op cit* note 72 at 13.

¹⁴⁵ Ibid at 9.

¹⁴⁶ Ibid at 2.

¹⁴⁷ Strode *et al* *op cit* note 78 at 47

¹⁴⁸ Mathews *op cit* note 72 at 2.

¹⁴⁹ Zuch, M., Mason-Jones, A.J., Mathews, C. & Henley, L. 'Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research' (2012) 12(3) *BMC International Health and Human Rights* at 1.

¹⁵⁰ Loveday *et al* *op cit* note 138 at 2.

adolescents cannot lawfully consent to participate in medical research, without the additional requirement of parental consent.

Practically, children and adults are ‘physiologically and anatomically’ different, and therefore, results obtained from adult participants in research cannot automatically be applied to adolescents or children.¹⁵¹ In addition, excluding adolescent participants will result in having a low pool of participants and ‘recruitment bias’ when conducting medical research on ‘sexual and reproductive health’ involving adolescents.¹⁵² The current position is unsustainable as it will negatively affect the long-term development of health research relating to adolescents.¹⁵³

Moreover, the shortcoming will affect even simple survey research where no harm can occur to children, such as obtaining research on eating disorders, hygiene or sexual behaviours of adolescents.¹⁵⁴ The NHA thus ignores the Children’s Act by preventing children from participating autonomously in various ‘health interventions’ which could benefit them.¹⁵⁵ A suggestion is for the NHA to specifically deal with consent requirements concerning adolescents involving sensitive topics in medical research.¹⁵⁶

Therefore, the Children’s Act is a more flexible approach to consent, recognising a child’s ‘evolving maturity and autonomy’, which should extend to section 71 of the NHA.¹⁵⁷ Labuschaigne *et al* suggest an amendment to the NHA where a child can consent to participate in medical research when they have ‘sufficient maturity and mental capacity to provide consent’, and conversely, with the consent of the parent or guardian where the minor lacks the mental capacity to provide consent.¹⁵⁸ The authors does not specifically define what level of maturity is required, but the broadened scope is favoured to advance medical research, especially for adolescents. The RECs should regulate this consent for medical research participation.

¹⁵¹ Worku *et al* op cit note 5 at 78.

¹⁵² Zuch *et al* op cit note 149 at 2.

¹⁵³ Loveday *et al* op cit note 138 at 2.

¹⁵⁴ Strode *et al* op cit note 78 at 47.

¹⁵⁵ Ibid.

¹⁵⁶ Worku *et al* op cit note 5 at 81.

¹⁵⁷ Labuschaigne *et al* op cit note 24 at 8.

¹⁵⁸ Ibid.

While the NDoH 2015 and NDoH 2024 permit researchers to apply for a ‘parental waiver’ in certain circumstances, it does not harmonise the situation with adolescents.¹⁵⁹ Strode and Essack point out that the dilemma between following the NHA (the law) or ‘ethical norms’ afforded in the ethics guidelines, creates ambiguity for RECs, resulting in RECs being inconsistent in approving research, which reduces the amount of ethical child health research that could be approved.¹⁶⁰ Therefore, situations where ethical waivers are permitted should be incorporated into the NHA to provide clarity and a legal basis for children to consent to participate in medical research autonomously.¹⁶¹

8. THE POPIA AND CONSENT REQUIREMENTS

The privacy of children’s personal information should be safeguarded to avoid any adverse effects when processing it.¹⁶² It will be explored if the POPIA can assist in harmonising the consent requirements relating to medical research in our law. Moreover, there is much debate between esteemed academics as to whether the POPIA even applies to medical research at all.

At the outset, section 1 of the POPIA defines consent as ‘any voluntary, specific and informed expression of will in terms of which permission is given to process personal information’.¹⁶³ A competent person must provide consent for a child, and the child must assent to participate in the research.¹⁶⁴ It is important to note that ‘continuous consent’ from the data subject should be obtained ‘before each research activity and phase’ of the study to qualify as lawful consent.¹⁶⁵

In line with the other legislation, a ‘child’ is defined as being younger than 18 years old.¹⁶⁶ In section 34 of the POPIA, a responsible party is not permitted to process the personal information of a child unless ‘the prior consent of a competent person’ is

¹⁵⁹ Strode and Essack op cit note 113 at 1.

¹⁶⁰ Ibid at 2.

¹⁶¹ Ibid at 5.

¹⁶² Burns and Burger-Smidt *A commentary on the Personal Information Act* (2018) at 96.

¹⁶³ The definition of consent, chapter 1.

¹⁶⁴ Hertzog, L., Wittesaele, C., Titus, R., Chen, J. J., Kelly, J., Langwenya, N., Baerecke, L., & Toska, E. ‘Seven essential instruments for POPIA compliance in research involving children and adolescents in South Africa’ (2021) 117(9/10) *S Afr J Sci.* at 2.

¹⁶⁵ Ibid at 3.

¹⁶⁶ Section 1 Definition of ‘child’ in the POPIA.

obtained.¹⁶⁷ The POPIA defines a ‘competent person’ as ‘any person who is legally competent to consent to any action or decision being taken regarding any matter concerning a child’.¹⁶⁸ This echoes section 11 of the POPIA, which states that data is only lawfully processed for a child if consent is provided by a ‘competent person’.¹⁶⁹ Consequently, the POPIA aligns with the NHA, which would not allow for an exemption for children to consent to medical research which contrasts with the Children’s Act, Choice Act, and the Ethics Guidelines in certain circumstances.

The POPIA is significant when considering medical research as it deals with the processing of ‘health information’ and ‘information in respect of children’.¹⁷⁰ According to Donnelly and Thaldar, the POPIA would also prohibit processing adolescents’ information for medical research because they would be included as children (part C of the POPIA) unless the conditions set out in the POPIA are satisfied.¹⁷¹ The authors argue that an HREC cannot lawfully waive consent beyond what the POPIA permits.¹⁷² Similarly, this argument extends to the NHA, a prevalent issue being dealt with. As an alternative regarding the POPIA, the authors consider whether the exceptions in the POPIA could be applied to medical research in minors.¹⁷³ These exceptions will be explored.

a) The public interest

There are exceptions where a child’s information can be processed without the consent of a competent person. In terms of section 27(1)(d)(i) and section 35(1)(d)(i) of the POPIA, special personal information and children’s personal information can be processed for medical research of minors without consent if ‘it serves a public interest and the processing is necessary for the purpose concerned’. Thaldar and Townsend suggest that ‘special personal information’ applies to medical research.¹⁷⁴

The Information Regulator has the authority to permit a responsible party to process the personal information of a child if it is in the ‘public interest’ *and* ‘the appropriate

¹⁶⁷ Section 35(1)(a) of the POPIA.

¹⁶⁸ Section 1 of the POPIA.

¹⁶⁹ Section 11(1)(a) of the POPIA.

¹⁷⁰ Donnelly and Thaldar op cit note 1 at 2.

¹⁷¹ Ibid.

¹⁷² Ibid.

¹⁷³ Ibid at 3.

¹⁷⁴ Thaldar and Townsend op cit note 91 at 15.

safeguards have been put in place' to protect the child's personal information.¹⁷⁵ However, the POPIA fails to specify the requirements for meeting the 'appropriate safeguards' provision and should provide clarity.¹⁷⁶ Additionally, there is a proviso that 'sufficient guarantees' must be implemented 'to ensure that the processing does not adversely affect the individual privacy of the child to a disproportionate extent'.¹⁷⁷ Determining what is considered 'disproportionate' under POPIA must be evaluated case-by-case, as the act does not guide in this regard either.¹⁷⁸ Accordingly, research involving children faces significant challenges in complying with the POPIA, particularly in determining what measures are sufficient to safeguard children's personal information.¹⁷⁹ As a consequence, the additional legislative requirements can become burdensome for researchers.¹⁸⁰

The Information Regulator drafted a guidance note on processing children's information with section 35(2) of the POPIA to assist with processing children's information.¹⁸¹ As the POPIA fails to define what constitutes being in the public's interests,¹⁸² the guidance note explains that it is a broad concept and should 'not be limited in its scope and application' but instead be considered on a 'case-by-case basis'.¹⁸³ Further, any outcome must benefit the public, not simply one person, and should be 'pursued in the spirit of equality and justice'.¹⁸⁴

The guidance note on processing children's information prescribes that 'appropriate safeguards' need to be undertaken by the responsible party in terms of section 19(1) of the POPIA.¹⁸⁵ These include the responsible party implementing measures identifying all reasonable risks arising from possessing the information, establishing and maintaining the 'appropriate safeguards' against any foreseeable risks, verifying and implementing the precautions effectively and updating them against new risks.¹⁸⁶ Moreover, the responsible party has to ensure that the rules and regulations specific

¹⁷⁵ Burns and Burger-Smidt op cit note 162 at 108; Section 35(2) of the POPIA.

¹⁷⁶ Ibid at 98.

¹⁷⁷ Section 35(1)(d)(iii) of the POPIA.

¹⁷⁸ Burns and Burger-Smidt op cit note 162 at 98.

¹⁷⁹ Hertzog *et al* op cit note 164 at 1.

¹⁸⁰ Ibid.

¹⁸¹ Information Regulator Guidance Note on Processing of Personal Information of Children.

<https://infoeregulator.org.za/wp-content/uploads/2020/07/GuidanceNote-Processing-PersonalInformation-Children-20210628-1.pdf> (accessed 3 January 2023).

¹⁸² Ibid para 4.2.1.

¹⁸³ Ibid para 4.2.2.

¹⁸⁴ Ibid.

¹⁸⁵ Ibid para 4.3.1.

¹⁸⁶ Ibid para 4.3.2.1 to 4.3.2.4.

to an industry or profession regarding 'security practices and procedures' are adequately complied with.¹⁸⁷ This implies that all legislation and guidelines concerning medical research and data security must be followed when conducting medical research involving children to abide by the POPIA, including consent requirements to participate in medical research.

To clarify, medical research in the public interest does not need to benefit the entire South African population - it could focus on addressing a specific health concern affecting a particular group within the larger population of South Africa, ultimately serving the public interest.¹⁸⁸ Thaldar and Townsend propose that medical research is always in the public interest.¹⁸⁹ The authors argue that medical research offers innovative solutions to medical problems.¹⁹⁰ Further, acknowledging the importance of human rights, the authors advocate for 'improved health', which supports human dignity.¹⁹¹ This is relevant especially to adolescent research.

The POPIA places significance on the public interest, especially for research. In this manner, more stringent acts, such as the NHA, better protect children's privacy because they are inflexible and do not have any exceptions. While the Children's Act focuses on the child's maturity to give consent, it might better protect the individual child's rights as the public interest exemption negates consent requirements entirely and places reliance on the Information Regulator.

b) Section 3(2)(a) of the POPIA

There is much debate about whether the POPIA applies when conducting health research. Section 3(2)(b) of the POPIA states that 'if any other legislation provides for conditions for the lawful processing of personal information that are more extensive than those set out in Chapter 3, the extensive conditions prevail'. Donnelly and Thaldar propose that when considering any legislation that appears to alleviate the requirements for child consent, the consent provided when processing personal

¹⁸⁷ Ibid Children para 4.3.3.

¹⁸⁸ Thaldar and Townsend op cit note 91 at 17-18.

¹⁸⁹ Ibid at 19 and 23; Section 37(2)(e) of POPIA.

¹⁹⁰ Ibid at 23.

¹⁹¹ Ibid; Section 27(1)(a) of the Constitution.

information will still have to be consistent with section 3(2)(a) of the POPIA, which ensures that any legislation complies with the standards of the POPIA.¹⁹²

Conversely, Bronstein and Nyachowe argue that when dealing specifically with medical research, the POPIA is not applicable owing to the existence of more 'extensive sectorial legislation' that regulates medical research.¹⁹³ The authors argue that the sectoral legislation for medical research offers more comprehensive guidelines and conditions for obtaining a child's consent than the POPIA.¹⁹⁴ Moreover, when there is a complaint against a researcher, an established REC with the requisite specialist knowledge should address the complaint rather than the Information Regulator, who would need more expertise to determine a medical matter.¹⁹⁵

Thaldar disagrees with their approach.¹⁹⁶ Firstly, Thaldar challenges the authors' suggestion that sectorial legislation is 'more extensive' simply owing to the sheer abundance of the legislation and suggests that on their interpretation, the focus should be on the 'substance' of the laws rather than their volume.¹⁹⁷

Further, Thaldar criticises Bronstein and Nyachowe for incorrectly equating the sectoral legislation with the conditions set out in the POPIA.¹⁹⁸ Therefore, Thaldar argues that the comparison should be individual conditions in the POPIA compared to other specific legislation, not health research sectorial legislation generally.¹⁹⁹

In response, Bronstein and Nyachowe maintain their position.²⁰⁰ In summary, the authors argue that it is problematic to adopt Thaldar's 'direct conflict test' because an unsystematic 'new regulatory scheme' would be developed through this 'process of comparison', which does not align with what the legislature intended when an already comprehensive system exists that regulates medical research.²⁰¹ Further, it is

¹⁹² Donnelly and Thaldar op cit note 1 at 2.

¹⁹³ Bronstein, V and Nyachowe, D T 'Streamlining regulatory processes for health researchers: To what extent does POPIA apply?' (2023) 113(8) *S Afr Med J* 1319 at 1319.

¹⁹⁴ Ibid at 1320.

¹⁹⁵ Ibid at 1321.

¹⁹⁶ Thaldar, D W 'POPIA does indeed apply to health research: A response to Bronstein and Nyachowe' (2023) 113(11) *South African Medical Journal* 1453-1455 at 1453.

¹⁹⁷ Ibid.

¹⁹⁸ Ibid.

¹⁹⁹ Ibid.

²⁰⁰ Bronstein, V and Nyachowe, DT 'Building coherence in the regulation of health research: A reply to Thaldar' (2023) 113(11) *South African Medical Journal* 1455-1457 at 1455.

²⁰¹ Ibid.

incorrect that a specific data subject's rights should precede broader societal interests in advancing medical research.²⁰²

Therefore, the POPIA does not help create harmony regarding the consent requirements when children participate in medical research. If anything, it stirs up a more significant debate about whether the POPIA should even apply to medical research. Suppose one follows Mathew's notion that simple health questionnaires cannot fall under medical research - In this regard, the POPIA would be a hurdle for health questionnaires constituting non-medical research in the strict sense, as the POPIA would then be applicable. In that case, adolescents would still be unable to consent to participate without the consent of their parents unless the Information Regulator deems the research in the public interest. Similarly, the Information Regulator can then be likened to the REC, who can waive consent for their information to be processed without a competent person.

9. INTERNATIONAL HEALTH RESEARCH INVOLVING ADOLESCENTS

Considering international health research involving children, in Mexico, girls between 16 and 20 years old were permitted to consent to participate in health studies, where they were sufficiently informed about the study and could give lawful voluntary consent.²⁰³ This research concerned sexual and reproductive health.²⁰⁴ Briefly, this research is critical in lower and middle-income countries (which is also relevant in South Africa), where there is a high rate of teenage pregnancies and sexually transmitted diseases in adolescents, usually associated with gender-based violence.²⁰⁵ The girls were recruited by female research assistants who were waiting for treatment in the community health centre, who then explained that the research was voluntary and it would not affect the treatment that they would receive from the health centre should they accept or reject participation in the research.²⁰⁶ This research was approved by the IRBs at the University of California San Diego and the

²⁰² Ibid.

²⁰³ Servin, A.E.; Macklin, R.; Wilkerson, S.; Rocha-Jiménez, T.; Rangel, G.M.; O'Bryan, S.E.; Fisher, C.B. 'Tailoring Sexual Health Research Practices to Meet the Needs of Adolescent Girls in Low- and Middle-Income Countries: Findings from Mexico' (2024) 4 *Adolescents* 158–170 at 160.

²⁰⁴ Ibid at 158.

²⁰⁵ Ibid.

²⁰⁶ Ibid at 160.

Universidad Xochicalco, Tijuana, Mexico, who approved that parental consent be waived owing to ethical considerations.²⁰⁷

The relationship between the participant and the researcher played a fundamental role in achieving ethical and better-quality research.²⁰⁸ It was notable that when participants genuinely feel safe and respected, they are more inclined to share their genuine experiences, which results in more successful research.²⁰⁹ Significantly, the research outcome illustrates that the girls feel empowered when participating in research that affects their health and well-being and that a parent's consent hinders research for sensitive topics that can lead to the development of solutions to their problems.²¹⁰ This reiterates the necessity to amend our laws.

Interestingly, the Mexican Health Ministry established a 'Youth Advisory Board' consisting of 50 adolescent girls (15-18 years old) from schools surrounding the community health centres, encouraging girls to participate in issues affecting them and, ultimately, policymaking.²¹¹ Therefore, the study also highlights the importance of community involvement and implementation of advisory boards when dealing with sensitive topics, ensuring that the research is ethical, respects one's culture, and protects children's rights.²¹² When this is achieved, adolescents can participate without parental consent in health research. South Africa could also establish committees in townships and schools to drive health education and partner with nonprofit organisations to assist in this much-needed research.

In an international study on adolescent obesity and policy development, researchers recruited participants between the ages of 16 and 18 years old, and most participants from Europe could consent themselves lawfully without parental consent, except in Poland and Portugal.²¹³ Noteworthy is that each country obtained ethical approval for the study from their respective institutions according to their laws.²¹⁴ An outcome

²⁰⁷ Ibid at 161.

²⁰⁸ Ibid at 164.

²⁰⁹ Ibid.

²¹⁰ Ibid at 166.

²¹¹ Ibid at 161.

²¹² Ibid at 166.

²¹³ Samdal O, Budin-Ljøsne I, Haug E, Helland T, Kjostarova-Unkovska L, Bouillon C, Bröer C, Corell M, Cosma A, Currie D, Eriksson C, Felder-Puig R, Gaspar T, Hagquist C, Harbron J, Jåstad A, Kelly C, Knai C, Kleszczewska D, Kysnes BB, Lien N, Luszczynska A, Moerman G, Moreno-Maldonado C, NicGabhainn S, Pudule I, Rakic JG, Rito A, Rønnestad AM, Ulstein M, Rutter H, Klepp KI. 'Encouraging greater empowerment for adolescents in consent procedures in social science research and policy projects' (2023) 24 *Obesity Reviews* at 4.

²¹⁴ Ibid.

discussed in the study suggested by Samdal *et al* is that research classified as unharmful to children by an ethics committee is that children from 12 should be able to consent themselves to participate, which would align with the UNCRCs.²¹⁵ However, to achieve this, the ethics committee must be knowledgeable in 'developmental psychology' to adequately assess a child's maturity and ascertain if any emotional or physical harm to a child could occur in that specific study to the child.²¹⁶ Consequently, the authority would lie with an ethics committee to permit a child as young as 12 years old to consent to participate in research. Similarly, the NHA could align itself with the UNCRC to recognise that children are constantly developing to encompass the ability to make informed decisions independently.²¹⁷

10. CONCLUSION AND RECOMMENDATIONS FOR SOUTH AFRICAN LAW

The legislature must consider incongruencies in our law to create the required harmony for medical research involving children. Medical research should focus on promoting children's Constitutional rights, including 'basic health care' and 'access to healthcare service'.²¹⁸ In this manner, children should appropriately be involved in advancing medicine for them, which can only be achieved through medical research.

Most importantly, the NHA's definition of 'health research' needs further categorisation, setting out expressly what type of research it refers to (e.g., questionnaires, observational research, clinical trials, etc.) and what consent criteria are required for children to participate in such medical research.

Our legislation is not tailored to allow mature children to provide independent consent. This is seen explicitly in the case of adolescents, where adolescents with the requisite maturity should be able to participate in medical research without having to obtain the consent of their parents or guardians. The Children's Act was enacted after the NHA, and it gives specific attention to children's rights and considers their decision-making abilities, making it more applicable and forceful than the NHA as it is a more recent and developed act.²¹⁹ Therefore, the weight and intention of the Children's Act should

²¹⁵ Ibid at 7.

²¹⁶ Ibid at 8.

²¹⁷ Loveday *et al* op cit note 138 at 5.

²¹⁸ Strode *et al* op cit note 78 at 47.

²¹⁹ Loveday *et al* op cit note 138 at 3.

be extended to the NHA and the POPIA to appreciate the evolving capabilities of children and differentiate between adolescents and younger children.

The dilemma of child consent in medical research is international. This is supported by the fact that many countries have failed to legislate when adolescents can consent to participate in medical research, yet they have legislated when a child can autonomously consent to medical treatment, where there is a potentially greater risk of harm to the child.²²⁰ This is illustrated in the Children's Act. To remedy any incongruencies, the Children's Act could be amended to incorporate specific provisions about health research.²²¹

Owing to these legal 'gaps', Mathews argues that there is no legal requirement for a parent to consent to an adolescent to participate in health research which is 'based on lived experience', as there is no legal principle that dictates that a parent is lawfully required to provide their consent to an adolescent in this research environment.²²² Based on this line of reasoning, research involving adolescents cannot lawfully require parental consent as this was not envisaged by legislation when it is so mundane and the risk to adolescents is absent. Accordingly, to bring about clarity, legislation must be drafted and enacted to lawfully permit adolescents over 12 years old to consent to participate in 'non-clinical medical research' themselves and a proviso that parents cannot invalidate such consent either.²²³ Conversely, parental consent should be obtained when there is a risk of harm to a child.

Additionally, the legislature should state whether it intended to exclude medical research from the applicability of the POPIA owing to the sectorial legislation and research exemptions in the POPIA or when its conditions of processing information should apply.²²⁴ This is specifically relevant to mundane health questionnaires and adolescents, which could fall beyond the scope of research as envisaged in the POPIA, in which case, the POPIA is applicable.

In the interim, there must be open communication between researchers and RECs to discuss consent processes and circumstances where parental consent can be waived

²²⁰ Mathews op cit note 72 at 16.

²²¹ Worku *et al* op cit note 5 at 82.

²²² Mathews op cit note 72 at 16.

²²³ Ibid at 43.

²²⁴ Bronstein and Nyachowe op cit note 193 at 1319.

in medical research involving children.²²⁵ The development of precedents where it is accepted that parental consent can be waived will make it easier for researchers to recognise when consent is required and when it is not.²²⁶ This can be achieved by the NHREC working with RECs to draft acceptable procedures when conducting medical research involving children.²²⁷ Owing to the NDoH 2024, the responsibility will lie with RECs to justify when parental consent can be ethically waived until our laws are expressly amended to bring clarity. Conversely, this approach may be reasonable in principle but contradicts when children are to participate in medical research according to the NHA, leading to RECs acting beyond the scope of the law.

In conclusion, different consent requirements for child participation apply to various situations and types of medical research. Adolescent participation is negatively affected by the strict NHA requirements. Harmonising our laws is required for medical research to develop and solve medical problems involving children in South Africa.

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²²⁵ Loveday *et al* op cit note 138 at 4.

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