LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
CONSENT TO PARTICIPATE IN RESEARCH				
Current Law				
Section 12(2)(c) of the Constitution of the Republic of South Africa Act 108 of 1996 provides that every person has the right not to be subjected to medical or scientific experiments without their informed consent	The Constitution is supreme law and this provision would apply to all medical research on children.	No child may be subjected to research without informed consent having been provided for that child's participation in research. Van Oosten argues that the use of the word "their" means research may only take place on competent persons – ie children cannot participate in research. Van Wyk suggests a broader interpretation that research must take place with appropriate consent, which may include proxy consent in the case of children and research.	The constitutional provision provides broad protection for children from participating in research without informed consent. However, it does not provide us with details of, for example, what falls under 'medical or scientific experiment' (Van Wyk argues that the terms research & experimentation have similar meanings) nor who would consent for a child to participate in research.	Legislation and/or ethical guidelines can provide the details of the participation of children in research, in accordance with the constitutional principles outlined in this section.
S39(4)(b) of the Child Care Act provides for children over the age of	Some legal commentators argue that therapeutic research can be alikened	Some legal commentators argue that by implication, children over the age of	Strictly speaking the provision does not apply to consent to research, but to	This provision will be repealed by enactment of Children's Bill

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
14yrs to consent independently to medical treatment	to 'medical treatment'	14yrs can consent to therapeutic research.	consent to medical treatment. The Act fails to provide a definition of medical treatment.	
In terms of s39 of the Child Care Act, a parent or guardian must consent to medical treatment in the case of children below the age of 14 years.	As above.	Some legal commentators argue that by implication, children under the age of 14yrs need the assistance of a parent or guardian in order to consent to participate in therapeutic research	As above.	As above.
In terms of s53(1) read with s53(3) of the Child Care Act, a person who is given custody of a child in terms of the Child Care Act or s290 of the Criminal Procedure Act has the right of control over a child, which does not include the power to consent to the performance upon or the provision to the child of medical treatment which is attended with serious danger to life	Some legal commentators argue that therapeutic research can be alikened to 'medical treatment'.	Some legal commentators may argue that by implication, as a person who has control over a child in terms of the Child Care Act or Criminal Procedure Act has the right to consent to medical treatment which is not attended with serious danger to life, that person may also consent for the child to participate in therapeutic research which is not attended with serious danger to life.	Strictly speaking the provision does not apply to consent to research, but to consent to medical treatment. Many children in South Africa are without parents or guardians, and have not been placed formally in the custody of another person as required by the Child Care Act and Criminal Procedure Act and therefore no-one would be in a position to consent for non-serious medical treatment	This provision will be repealed by the enactment of the Children's Bill.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
			and therapeutic research.	
Future Law				
S71(1) of the National Health Bill provides that research may only be conducted with written consent of the person after he or she has been informed of the objects of the research and any possible positive or negative consequences on his or her health.	Although s71(2) and (3) contain provisions specific to research on children, we submit that the general provisions set out in s71(1) would also apply to research on children.	All persons consenting to research involving children (parent, guardian and child) must be informed of the objects of the research, and any possible positive or negative consequences to health, before providing written consent to the research.		
S71(2) of the National Health Bill provides that therapeutic research on a minor may only take place (a) if it is in the best interests of the minor; (b) in such manner and on such conditions as may be prescribed; (c) with the consent of the parent or guardian of the child; and (d) if the minor is capable of understanding, with the	These provisions apply to research or experimentation on a minor for therapeutic purposes	A parent or legal guardian must consent for a child of any age to participate in therapeutic research (if other conditions are met.) If a child is capable of understanding, then he or she must also give consent for participation in therapeutic research.	Best interests of a minor is not defined. Therapeutic purpose is not defined. Child is not defined, and is used interchangeably with minor. No custodian other than a parent or legal guardian may consent. No child may consent independently, regardless of age. Child may only participate in	We may need to explore the possibility of requesting the removal of s71 from the National Health Bill, although this is unlikely given the late stage of the development of the Bill. Other (fairly obstructive) possibilities are to challenge the provisions in court as unconstitutional, or ask for an order declaring them void for vagueness.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
consent of the minor.			decision 'if capable of understanding' and no details are given on how to assess understanding.	Alternatively, it may be possible to clarify and/or amend (to a limited degree) aspects of the Bill through input on the regulations to be enacted in terms of the Bill. Finally, it may be possible to request the drafters of the Children's Bill to repeal s71, through inclusion of a new provision re: consent for research on children.
S71(3)(a) of the National Health Bill provides that non-therapeutic research on a minor may only take place: (a) in such manner and on such conditions as may be prescribed; (b) with the consent of the Minister; (c) with the consent of the parent / guardian of the child; (d) if the child is capable of understanding, with the consent of the child.	These provisions apply to research or experimentation on a minor for non-therapeutic purposes	The Minister and a parent or guardian must consent for research to take place on a minor for non-therapeutic purposes. If the child is capable of understanding, the child must also consent to the research.	Non-therapeutic purpose is not defined. The distinction between therapeutic and non-therapeutic purposes is problematic. No custodian other than a parent or guardian may consent. No child may consent independently, regardless of age. Child may only participate in decision if 'capable of understanding'	As above

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
S71(3)(b) of the National Health Bill provides that the Minister may not consent to non-therapeutic research on a minor if (a) the research could achieve its purpose by being conducted on adults; (b) the research is not likely to significantly benefit minor with the particular condition/disease/disorder (c) the reasons for consent to the research are against public policy; (d) the research poses a significant risk to minor; OR (e) the research poses some risk which is not outweighed by the potential benefit	As above.	The Minister may not consent to non-therapeutic research if any one of the provisions in s 71(3)(b)(a) – (e) is met.	Condition (b) may create some confusion regarding the understanding of non-therapeutic research, in the case of research on healthy minors that confers no benefit. Condition (c) will require the Minister / administrative body to whom the power is delegated to understand the application of 'public policy' Condition (d) creates a lower risk standard than that of existing ethical guidelines	As above.
Section 8(1) of the National Health Bill provides for the rights of health users to participate in decision making regarding their health. According to s8(2)(a) – (b), if the informed consent required by s7 for a health	Section 1 of the Act defines a user (including a child) as 'a person receiving treatment in a health establishment or using a health service'. The definition appears to exclude a child participating in research,	The provisions which allow for the right of health users to participate in decision making regarding their health do not appear to apply to research. Also, the provisions providing for consultation with a child before informed consent	Although the National Health Bill makes provision for the participation of all users (including children) in decision making regarding their health; as well as the consultation and the provision of information to children in the case where	

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
service is given by a person other than the user, the person must, if possible, consult with the user and if the user is capable of understanding, must also must inform the user of his/her health status, diagnostic and treatment options, benefits, risks and consequences associated with each option and the right to refuse health services.	unless it could be argued that therapeutic research falls under the ambit of 'treatment'. A health service is also defined in such as way as to exclude research, so that the s7 provisions relating to informed consent for health services would not appear to apply to informed consent for research purposes.	for a health service is given by a parent or guardian appear not to apply to research.	informed consent for a health service is given by a parent or guardian, these provision do not appear to apply to children participating in research. This means that the s71 provisions, which allow only for the consent of the child *if they are capable of understanding* are the only provisions which apply to the participation of children in research. In other words if children do not have sufficient understanding then they do not have to provide their consent and there is no mechanism for ensuring that their views are heard.	
In terms of s135(2)(a) of the proposed Children's Bill a child of 12 yrs of age with the maturity and mental capacity to understand the benefits, risks, social & other	Some legal commentators would argue that therapeutic research can be alikened to 'medical treatment'. However, if the provisions in the National Health Bill relating	Some legal commentators may argue that, in terms of this provision and in the absence of laws dealing specifically with consent to research, a child of 12 yrs of age with the maturity	Strictly speaking, the provision does not apply to consent to research, but to consent to medical treatment. Medical treatment is not defined. This means that in all likelihood s71 of	It may be possible to lobby the drafters of the Bill to include provisions for consent to (medical) research in the Bill. The provisions would ideally have to repeal the

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
implications, may consent independently to medical treatment.	specifically to consent for research are enacted, it would be difficult to sustain this argument.	and mental capacity to appreciate the implications thereof, may consent independently to therapeutic research.	the National Health Bill would take precedence in the case of consent to therapeutic (and non-therapeutic) research.	proposed provisions in the National Health Act 61 of 2003. Need to discuss implications of other forms of research
In terms of s135(3) of the Children's Bill a parent or primary care-giver may consent to medical treatment for a child who is under the age of 12 years, or who doesn't have the necessary maturity / mental capacity to understand the benefits, risks, social implications. A primary care-giver is defined as a (a) person with and exercising parental rights and responsibilities (b) person who cares for a child with consent of person with parental rights and responsibilities (c) foster parent / kinship care-giver (d) child & youth care	As above.	Some legal commentators may argue that, in terms of this provision and in the absence of laws dealing specifically with consent to research, a child below 12 years of age or a child who didn't have the maturity / mental capacity to appreciate the matter, would need the consent of a parent or primary care-giver in order to participate in therapeutic research	As above.	As above.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
worker working where child has been placed (e) person caring for child in temporary safe care, but excluding a person who receives remuneration / grant for doing so.				
In terms of s32(1) – (3) of the s75 Children's Bill a person who has no parental rights & responsibilities in respect of a child but who voluntarily cares for a child either indefinitely, temporarily or partially, including a care-giver who otherwise has no parental rights and responsibilities in respect of a child may, whilst the child is in that person's care, exercise parental rights & responsibilities including consent to any medical treatment of a child if such consent cannot be obtained from the parent or primary care-giver. The court can, however, limit this person's parental	Some legal commentators would argue that therapeutic research can be alikened to 'medical treatment'. However, if the provisions in the National Health Bill relating specifically to consent for research are enacted, it would be difficult to sustain this argument.	Some legal commentators may argue that, in terms of this provision and in the absence of laws dealing specifically with consent to research, a child below 12 years of age or who didn't have the maturity / mental capacity to appreciate the matter could get the consent of a care-giver as described in s32(1) for participation in therapeutic research.	Strictly speaking, the provision does not apply to consent to research, but to consent to medical treatment. Medical treatment is not defined. This means that in all likelihood s71 of the National Health Bill would take precedence in the case of consent to therapeutic (and non-therapeutic) research.	It may be possible to lobby the drafters of the Bill to include provisions for consent to medical research in the Bill. The provisions would ideally have to repeal the proposed provisions in the National Health Act 61 of 2003.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
rights & responsibilities.				
Section 130(1) of the Children's Bill provides that a child may only be tested for HIV when (a) it is in the best interests of the child; or (b) the test is necessary to establish whether any person may be at risk of HIV infection due to coming into contact with any substance from the child's body that may transmit HIV	HIV testing may form part of research proceedings (for example, HIV vaccine research).	HIV testing of a child as part of a research proceeding would have to be established to be 'in the best interests of the child'.	Presumably, different considerations would apply in the case of repeated HIV testing for research purposes, compared with the case of HIV testing as part of a VCT service.	Group to discuss possible recommendations. It may be that the 'best interests' standard should only apply when consent to HIV testing is given by someone other than the child him or herself?
Section 130 of the Children's Bill provides that a child of 12 yrs or a child under 12 yrs with sufficient maturity to understand the benefits, risks & social implications may consent to an HIV test	As above	This provision implies that a child (any age) with the sufficient maturity to understand the benefits, risks & social implications may consent to an HIV test.	There are potential difficulties as it is unclear how this provision would apply in conjunction with the s71 provisions in the National Health Bill which require the consent of a parent/guardian for therapeutic and non-therapeutic research. Either specific consent to HIV testing could be separated out from general, informed consent to the research as a	Group to discuss possible recommendations.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
			whole; alternatively a parent/guardian would need to consent for all aspects of the research, in terms of the NHB provisions, which would include all HIV testing which formed part of the research.	
Section 31 of the s75 Children's Bill provides that before a person holding parental rights & responsibilities over a child takes any decision which is likely to change significantly, or have an adverse effect on a child's health, that person must give due consideration to any views & wishes expressed by the child, bearing in mind the child's age, maturity and stage of development.	In terms of this provision, a child's participation in research may be considered to be 'a decision which is likely to change significantly (or have an adverse effect on) a child's health.	Where a person holding parental rights & responsibilities over a child, such as a parent, guardian, & primary care-giver with parental rights & responsibilities, takes a decision which impacts on a child's health, such as providing for the child to participate in research, he or she must take into consideration the child's views (bearing in mind the age, maturity and stage of development of the child).	It is unclear why the section refers only to situations where a person holding parental rights & responsibilities over a child takes a decision, since other sections of the Bill allow for other persons (such as a primary care-giver, who may not always have parental rights and responsibilities over the child, in terms of the definition of primary care-giver in s1 of the Bill; and a care-giver as defined in s31 of the Bill) to take decisions regarding a child's health care. There is also a slight difference between this provision, which provides that a child's views must	

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			always be considered in major decisions (such as participating in health research), and s71 of the NHB which allow for the consent of the child *if they are capable of understanding*.	
CONFIDENTIALITY FOR CHILDREN IN RESEARCH				
<u>Current Law</u>				
The Constitution of the Republic of South Africa Act protects the right to privacy (s14).	The right to privacy applies to all persons, and would also apply to children participating in research.	Children have the right to privacy / confidentiality regarding their participation in research, as well as their health status and treatment during research.	It is unclear when a child's right to confidentiality is exercised by his/her parent or guardian, and when the child him or herself may exercise this right. Legal commentators have argued that, in terms of medical confidentiality, where a child is able to consent to health services, he or she is then able to exercise the right to confidentiality with regard to that treatment. Following this interpretation would mean that in terms of the NHB provisions, a child's parent	Need a clear understanding of what a child's right to privacy in research means, who has access to his or her health information?

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
			or guardian would exercise the child's right to confidentiality while participating in research. Additionally, it is unclear when the right to confidentiality should be limited, although the s36 limitation clause would apply.	
South African common law protects the *dignitas* of every person, which includes the right to privacy.	As above.	As above	As above. Grounds of justification for breaching the right to privacy could include necessity, consent or statutory authority.	As above

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
<u>Future Law</u>				
Section 14(1) of the National Health Bill gives every user the right to confidentiality regarding his or her health status, treatment or stay in a health establishment. A user is defined as a person receiving treatment in a health establishment or using a health service, and where the person receiving treatment is below 14 years of age, includes his or her parent or guardian.	Legal commentators may argue that therapeutic research falls under the ambit of 'treatment', in which case a child participating in research falls within the definition of a 'user'.	This would mean that a child participating in therapeutic research has the right to confidentiality. This right would be exercised by the child, if the child is over the age of 14 years, and by the parent / guardian, if the child is below the age of 14 years.	If the interpretation above were to be argued it would still mean that the right to confidentiality in non-therapeutic research would be unclear. Additionally, it would mean that a child of 14yrs participating in therapeutic research would have the right to confidentiality within the research, despite the fact that s71 required parental consent for participation in the research. A literal interpretation of the definitions of user and of health service in the Bill in fact appear to exclude participation in research. This makes it unclear as to how the right to confidentiality applies to therapeutic and non-therapeutic research, and who exercises the right on the child's behalf. It implies that a parent or guardian	

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
			would always exercise the child's right to confidentiality when a child of any age is participating in research. Primary care-givers are not mentioned.	

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
Section 14(2) of the National Health Bill provides that the right to confidentiality may not be breached unless the user consents in writing; a court order or law requires disclosure or non-disclosure presents a threat to public health.	As above	This would mean that a 14yr old child participating in therapeutic research would be protected from a breach in confidentiality (including to a parent / guardian) unless he or she provided written consent to the disclosure, or any of the other 2 conditions applied.	As above. Additionally, the provisions for disclosure are different to those set out in the Children's Bill, which allows for a breach of confidentiality 'in the best interests of the child'.	
Section 13 of the s75 Children's Bill gives every child the right to confidentiality regarding his or her health status, 'except when maintaining such confidentiality is not in the best interest of the child'.	Although not specifically stated, it can be argued that the right to confidentiality regarding health status applies equally to children participating in research.	Children participating in research have the right to confidentiality regarding their health status. No age limit is provided, but this right may be breached when it is considered to be 'in the best interests of the child'.	The provisions do not appear to place an age limit on a child's right to confidentiality, or to explain when a parent / guardian or primary care-giver would exercise this right. Also, our law provides existing limitations to the right to privacy – in terms of s36 of the Constitution and in terms of common law grounds of justification such as necessity, consent and statutory authority. It is unclear why the 'best interests of the child' standard should replace those provisions, rather than operating as the paramount	

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES
			principle in conjunction with existing provisions.	
RISK-BENEFIT ANALYSIS				
Future Law				
S71(2) of the National Health Bill provides that therapeutic research on a minor may only take place if it is in the 'best interests of the child'. Section 71(3)(b) of the Bill provides that the Minister may only consent to non-therapeutic research on a minor if it does not pose a significant risk to the health of the minor OR if there is some risk but it does not outweigh the benefit.	The provisions apply to both therapeutic and non-therapeutic research on a child.	There is a legal obligation to conduct a risk analysis, as well as a risk-benefit analysis, before non-therapeutic research on a minor may be approved. Therapeutic research is also required to undergo a 'best interests of the child' analysis.	It is unclear why the drafters of the NHB have required a 'risk-benefit' analysis in the case of non-therapeutic research, and a 'best interests' analysis in the case of therapeutic research. While it may well be that similar factors are considered in both cases, the use of the different terminology has served to confuse the matter.	

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES

IN SUMMARY:

CONSENT

- At present, there are no laws providing for who consents for a child to participate in medical research
- If we assume that current law regarding consent for medical treatment can be applied to the situation of consent to therapeutic research, then we could argue that children over the age of 14 years can consent independently to participate in treatment, and children under the age of 14 years need the assistance of a parent, (legal) guardian, or a person who has been granted control over a child in terms of a provision of the Child Care Act or s290 of the Criminal Procedure Act, to consent to therapeutic research.
- Current law does not appear to provide for the situation of who should consent for a child to participate in non-therapeutic research.
- The National Health Bill has been given the title Act 61 of 2003, is with the President, and is due for signing any day now according to sources within the Department of Health: Legal Department.
- Act 61 of 2003 contains legal provisions regulating consent for a minor to participate in medical research.
- According to the Act, in the case of therapeutic research, a parent or guardian must consent for a minor / child to participate in the research, no matter what the age of the minor is (A minor is currently defined in our law as being below 21 yrs of age, a child as below 18 years of age). Additionally, if a child is capable of understanding, he or she must also consent to participate in therapeutic research. There does not seem to be any provision for the participation of a child in the decision-making process, beyond consent if capable of understanding.
- Futhermore, in terms of non-therapeutic research, the Minister must consent to the research taking place, and a parent or guardian must consent for an individual child to participate in the research, no matter what the age of the child is. Additionally, if a child is capable of understanding, he or she must also consent to participate in non-therapeutic research. Again, there does not seem to be any provision for participation of the child in the decision-making process, beyond provision for dual consent if they child is capable of understanding.
- The Minister may not consent to non-therapeutic research on a minor if certain conditions outlined above are present. This would limit non-therapeutic research on minors.
- The Children's Bill aims to consolidate laws relating to the protection and welfare of children. However, while it contains extensive provisions relating to consent for medical treatment / operations, it does not deal specifically with consent for children to participate in research. This probably means that, if the provisions on consent to research on minors in the National Health Bill were enacted, these provisions would prevail.

LAW	APPLICATION TO CHILDREN & RESEARCH	IMPLICATION	GAPS / SHORTCOMINGS	POSSIBLE REMEDIES

- The Children's Bill proposes that a child of 12 years of age, with sufficient maturity / mental capacity to understand the matter, be able to consent to medical treatment. In the absence of the NHB provisions, it could be argued that the same child would be able to consent independently of a parent / primary care-giver to therapeutic research.
- In the case of a child under the age of 12 years or a child of any age but with insufficient maturity / mental capacity to understand the matter, a parent or primary care-giver can consent to medical treatment. In the absence of the NHB provisions, it could be argued that the same child would need the consent of his/her parent or primary care-giver to consent to therapeutic research. However, there is still provision in the Bill for consideration of a child's views (bearing in mind age, maturity, stage of development) in situations where a person holding parental rights/responsibilities (parent, guardian and sometimes primary care-giver) makes a major decision which would significantly change the child's health.
- The position with regard to consent to non-therapeutic research on a minor would still be unclear in terms of the Children's Bill, in the absence of the NHB provisions.
- **CONFIDENTIALITY**
- At present, there are no laws providing for confidentiality specifically in the research setting
- Our constitutional and common law protects the right to privacy. This means that all people, including children, have the right to confidentiality with regard to health information, including their health status and treatment, and their participation in a clinical trial.
- At what age children exercise this right on their own behalf, and at what age this right is exercised on a child's behalf by his or her parent or guardian is unclear in our constitutional / common law, but generally it has been linked with the age / stage at which a child can independently consent to a procedure.
- The National Health Bill provides that a child over the age of 14 years has the right to confidentiality with regard to medical treatment, and a child below the age of 14, together with the child's parent or guardian have the right to confidentiality regarding his or her health status, treatment etc.
- The Children's Bill provides every child (no age limit specified) with the right to confidentiality. This right may be limited 'in the best interests of the child'.
- **RISK-BENEFIT ANALYSIS**
- Present law does not provide specifically for a risk-benefit analysis to be undertaken before a child may participate in research.
- The National Health Bill provides for the use of the 'best interests of the child' standard to be applied to considerations of thereapeutic research on a minor, and a risk-benefit analysis for non-therapeutic research on a minor.