Consent for children participating in research

To the Editor: With reference to the article and more recent letter on the implications for researchers, service providers and policy makers of child consent in South African law,[1,2] I wish to put forward a different but more appropriate approach to consent for children participating in research. Although I agree that s71 of the National Health Act of 2003[3] is not in force, the Guidelines of the National Health Research Ethics Committee are.[4] The NHREC is quite clear when it comes to consent for children participating in research. Research should be of minimal risk and consent for minors must be obtained from the parents or legal guardian in all but exceptional circumstances (such as emergencies), as well from as the minor where s/he is competent to make the decision. This is consistent with international practice, and I urge all researchers and Human Research Ethics Committees to be compliant with this guideline in the meantime.

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4. South Africa. National Department of Health: Ethics in Health Research: Principles, Structures and Processes. Pretoria: Government Printer, 2006.

Slack, Strode and Essack reply: Professor Naidoo argues that an 'appropriate approach' to child research is that the 'research should be of minimal risk and consent for minors must be obtained from the parent or legal guardian in all but exceptional instances' and, moreover, that this is consistent with South African national ethical guidelines and international practice.

On the contrary, it is not clear why this proposal is appropriate in all instances, and our South African ethical-legal framework does not provide unqualified support for such a position.

Current South African ethical guidelines, including the *Good Practice* guidelines[1] and the general ethical guidelines *Structures, Principles and Processes*,[2] provide that in certain circumstances children are permitted to be enrolled in research that presents more than minimal risk. Where the research procedures hold out the prospect of direct benefit, there is no express cap on the risk level, although the risks must be reasonable in relation to the anticipated benefit (and appropriately minimised); and where the research procedures do not hold out the prospect of direct benefit, the risks must represent a minor increase over minimal risk.[3] This position is echoed in international frameworks, such as the Code of Federal Regulations in the USA.[4] Should children's participation in research be limited exclusively to minimal-risk research, it is difficult to see how children would ever be enrolled in clinical trials of experimental products.

Furthermore, in current South African ethical guidelines child participation in research is sometimes permissible even when parental or guardianship consent is not obtained, for example *Structures, Principles and Processes*[2] (correctly) allow older adolescents to participate in minimal-risk research with independent consent. The *Good Practice* guidelines[1] also recognise the ability of caregivers providing long-term day-to-day care of children to provide proxy consent in some instances. International frameworks also allow for waivers of parental consent in certain specific instances, and where sufficient safeguards are in place.

We do not dispute that in *all* instances of child research, research ethics committees must make complex determinations about whether the research presents acceptable risks to child participants; nor that in *many* instances of child research, proxy consent by an adult is most desirable and that in many instances proxy consent should be obtained from a parent/legal guardian.[5] However, we argue here that the situation is not as simple as the proposal set out by Professor Naidoo, and that any competent ethico-legal framework should be able to accommodate a broad range of health research proposals involving children.

Acknowledgements. The work of the HIV/AIDS Vaccines Ethics Group is funded by the South African AIDS Vaccine Initiative (SAAVI). The views expressed in this letter do not necessarily reflect those of SAAVI.

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Mini-slings – concern regarding marketing of these devices in South Africa

To the Editor: Aggressive marketing of medical devices impacts on the day-to-day practice of clinicians. The marketing of the mini-sling devices for stress urinary incontinence (SUI) in women is an area of major concern to us. SUI is the involuntary leakage of urine from the urethra with exertion, or on sneezing or coughing, and affects up to 35% of women.[1] It is a distressing condition and significantly impacts on quality of life.

Traditional interventions include pelvic floor exercises and open retropubic colposuspension. Ulmsten in 1995 introduced an effective minimally invasive option for surgically managing SUI, the 'tension-free vaginal tape' (TVT) (Gynecare, Ethicon, Somerville, USA).[2] This was followed by development of the transoburator-type sling, which avoided the risks of bladder, bowel and major vascular injury.[3] Both slings are made of synthetic mesh and are placed mid-urethrally, and their placement is the most commonly performed surgical procedure for SUI.

Long-term follow-up of Ulmsten's original series found an objective cure rate of 90% at 10 years. Level 1 evidence found efficacy to be equivalent to that of colposuspension. Meta-analysis has further shown equivalence in terms of cure between the trans-obturator and retropubic placement of mid-urethral slings.[4]

Mid-urethral slings therefore offer a highly efficacious minimally invasive surgical option with low postoperative morbidity. Device manufacturers have in the past 5 years introduced and strongly promoted eight further so-called 'mini-slings' that are claimed to be less invasive, and are placed via a small single vaginal incision.

There is little quality evidence to support the use of mini-slings. Nearly all the available studies show inferior efficacy. The most studied device, the TVT-Secure, was the subject of a 12-month outcome study