Countries around the world are developing HIV vaccines for use in general populations, and adolescents will, of necessity, need to be involved in this process. South Africa’s experience in this regard could be useful to Asian countries seeking to develop or revise their ethical-legal research framework on children. This article considers current South African law and its new framework for child research. It concludes with certain reflections on our experiences in trying to ensure that the ethical-legal framework creates a balance between protecting and empowering child research participants.

Introduction
South Africa is in the midst of a severe HIV epidemic, with current estimates that approximately 5 million people are infected\(^1\). Young persons are the most affected by the epidemic with an estimated 230 000 new infections occurring every year in persons between the ages of 15 – 24 \(^2\). In this context, preventive research that enrolls currently healthy children is critically important. If South Africa is to approve HIV vaccines for use in adolescents,
the national regulatory authority will require data on the safety and efficacy of the vaccine in this age group, necessitating child participation in trials (3). However, enrolling children in HIV vaccine trials is complex, particularly early safety trials that may be classed as “non-therapeutic”. While “non-therapeutic” studies are often defined as those that chiefly aim to generate scientific data and do not directly benefit volunteers, the distinction between therapeutic and non-therapeutic research is highly controversial (Levine, 1999).

There are many ethical-legal difficulties with the participation of children in so-called “non-therapeutic” research. In South Africa, the heart of the issue is that law and ethical guidelines have struggled to find a balance between the competing interests of protecting children from harm and empowering children to act autonomously. While the South African framework may be imperfect, it offers a template that can be improved upon. What follows is a brief exploration of this framework to inspire further reflection and future work, globally.

**Current Regulation of Health Research with Children**

Like most others, South Africa’s legal system protects young persons by limiting what they can freely choose to do. This means that an adult (usually a parent or a legal guardian) is given the authority to make certain decisions on behalf of the child. Although children have limited legal capacity there has, in recent years, been a greater focus on child participation in decision-making. This has resulted in laws being passed allowing children to make certain decisions independently before the end of childhood. For example, children can consent to medical treatment from the age of 14(4) and female children may consent to an abortion at any age (8).

There is also a move within the legal framework towards limiting the decision-making power of parents or legal guardians. For example, in many countries, laws now set the standard on how to discipline children. In other words, public policy considerations regarding what is acceptable parenting are now established in law rather than being exclusively parental prerogative.

Currently, South Africa does not have specific laws regulating research with children. Researchers and RECs have been guided by the general legal principles relating to medical treatment and the provisions in ethical guidelines (10). These guidelines protect children by limiting their autonomy and that of their parents. For example, some guidelines do not allow children (of any age) to consent independently to “non therapeutic” research and only allow parents to consent to “non-therapeutic” child research participation if it is observation research with a negligible risk (11). On the other hand, children of 14 years may participate in clinical trials without any proxy parental consent if these are deemed to be “therapeutic research” (10) regardless of risk level.
Future Regulation of Child Research

The National Health Act is a new law that will regulate research with human subjects. It provides that children may participate in “non-therapeutic” research if: they have the consent of their parent or legal guardian, if they give consent or assent themselves, and consent has been obtained from the Minister of Health for the research (s 71(3)). This Act empowers children to participate in non-therapeutic research beyond merely observational research. However, the drafters of the Act have included an onerous protection, namely that all non-therapeutic research of any risk level must be approved by the Minister of Health. This creates an additional layer of administrative scrutiny that could have been served by Research Ethics Committee review alone, will mean large volumes for ministerial approval, and possible delays in the review of such research. This, in some respects, detracts from the rights of children to participate in such research. Some will argue that limiting proxy consent for research participation to parents and legal guardians only (as the Act does) will exclude many worthy beneficiaries of research, such as orphaned children, from participation.

Reflections and Conclusions

It would appear that our past and future frameworks for regulation of child research have not achieved an appropriate balance between child participation and protection. The search is still on for principles and mechanisms to facilitate child participation to enable children to benefit from the development of new drugs and interventions whilst at the same time ensuring that children are not harmed by their increased participation. A sliding scale of risk associated with beneficial and non-beneficial research which triggers increasing procedural protections in the form of proxy consent and approval by a political figure is a possible alternative, such as the one employed in the United States Code of Federal Regulations. Countries looking to create an appropriate regulatory framework should consider the pitfalls of the South African framework and the promise of more balanced frameworks. The HIV AIDS Vaccine Ethics Group is funded by the South African AIDS Vaccine Initiative.
References


4) Child Care Act 1983, No. 74, s39.


8) s 5, termination of Pregnancy Act, No. 92 1996.

9) National Health Act, No. 61 of 2003.
