Minors in research: consent issues

Prof M Labuschaigne
Department of Jurisprudence
School of Law
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Legal framework

- National Health Research Ethics Council established in 2006 in terms of s 72 of the National Health Act (NHA).
- Section 73(1): every organisation/institution, health agency and health establishment at which health and health-related research involving human participants is conducted, **must establish or have access to a registered Human Research Ethics Committee**.
- RECs that review research involving human participants must register with the NHREC.
- **For RECs not registered/yet registered with the NHREC, the Guidelines will nevertheless apply and will be legally binding**
- Among the NHREC’s duties:
  - to set norms and standards for health research involving humans and animals, as well as for conducting clinical trials;
  - to determine guidelines to facilitate best practice for research ethics committees
Legal status: 2015 DoH Guidelines

- Regulations relating to research with human participants (2014):
  - health research that involves human participants **must** comply with the Department of Health national ethical guidelines for research with human participants **at a minimum**

- Recognition of the ethical guidelines as a **minimum mandatory benchmark** = guidelines became legally binding

- Which would prevail in case of conflict/ambiguity: DoH Guidelines, the Regulations relating to Research with Human Participants, or the provisions in the National Health Act?
Research on a living person only be conducted (a) in the prescribed manner; and (b) with the 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.

S 71(2): Where research on a minor is for a therapeutic purpose, the research may only be conducted: (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 consent of the minor.

For non-therapeutic purposes: (i) in such manner and on such conditions as may be prescribed; (ii) with the consent of the Minister; (iii) with the consent of the parent or guardian of the minor; and (iv) if the minor is capable of understanding, the consent of the minor.

Minister’s consent or delegated consent are limited by certain factors
How to resolve the impasse?

- S 71 of the NHA provides that, in addition to consent and other requirements, both therapeutic and non-therapeutic research with minors may be conducted “in such manner and on such conditions as may be prescribed”

- The meaning of “as may be prescribed” in s 71 of the NHA refers to prescribed regulations relating to research with human participants, in this instance the 2014 Regulations, which determine the DoH Guidelines to be the minimum standard

- Thus: both the NHA provisions, as well as the 2014 Regulations AND the DoH Guidelines are legally all binding on the same level
Law of statutory interpretation in case of conflict

- Role of the law of statutory interpretation in instances of legal ambiguity or conflict

- *Bato Star Fishing Ltd v Minister of Environmental Affairs and Tourism* (2004)(CC):
  - The 1996 **Constitution is the starting point** in interpreting any legislation
  - the interpretation that is placed upon a statute must, where possible, be one that **would advance at identifiable value(s) enshrined in the Bill of Rights**
  - Emerging trend in statutory construction is to **have regard to the context in which the words occur**, even where the words are construed are clear and unambiguous
Section 39 of the Constitution

• When interpreting a bill of rights a court must promote the values that underlie an open and democratic society based on human dignity, equality and freedom

• Interpretation involves more than analysing the particular provision in question

• To interpret a text in its context, includes the intra-textual context (the enactment as a whole, including its unique structure) as well as the extra-textual context (the rest of the existing law and other contextual considerations that might be applicable)

• Text and context matter
Section 39 of the Constitution

• S 39 also provides that when interpreting the Bill of Rights, a court:
  – May consider foreign law
  – **Must** consider international law
• Effect of this is that an international human rights framework (e.g., CRC) which SA has signed and ratified must be considered and may assist with the interpretation of a conflict between competing constitutional rights, in this instance those pertaining to the consent of minors in research
• International legal approaches will hence become relevant
Statutory interpretation (cont)

- Unless the contrary is clear, it is presumed that the legislature does not intend legislation which is futile or nugatory
- ‘The principle of effectual and purposeful legislation’ (Hahlo & Kahn)
- Since statutory interpretation is a purposive activity, this presumption is an acknowledgement that legislation has a functional purpose and object
- If there is a conflict between national and provincial legislation, national usually trumps the provincial legislation
- If two different pieces of legislation at the same level are in conflict, they must be read together
- If reading the different pieces dealing with the same issue together doesn’t resolve the problem, an argument may be made the later provision(s) impliedly override(s) the earlier version
Conclusion

- Should attempt to **harmonise the conflicting positions** to align with the Constitution
- The **one closest to giving effect to the Bill of rights** will be the preferred provision
- The Children’s Act that deal with consent of minors in other contexts is highly relevant, as these are best aligned with the evolving rights of self-determination of minors
- Balancing of ethical framework with constitutional values of dignity, respect for persons, equality, autonomy and the rights to human dignity; freedom and security of the person (autonomy); academic freedom (scientific advancement) is required
- In the interim, case by case basis – rigorous review by RECs necessary
- Best practices should be shared among RECs
- Sensitisation of HRECs important – ‘one size fits all’ not possible due to varying contexts