Minors in research: consent issues

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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?

National Health Act: s 71

- 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 occu**r, 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 (eg 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 intent 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