RESEARCH INVOLVING CHILDREN

1. In South African law, a 'child' is defined as a person younger than 18 years old (National Health Act 61 of 2003; Children's Act 38 of 2005).

2. National ethics guidelines designate children participating in research as a vulnerable group (DoH, 2015) and require that the risk of their participation is reflected on carefully by researchers in terms of inclusion and exclusion. Two guiding questions:

   - Is the research essential to understanding children's perspectives on matters affecting/ impacting their health and well-being?
   - Does the research pertain directly to children's health conditions or the prevention thereof?

3. In research involving children as participants, both **parental consent** and **children's assent** are required (unless there are justifiable legal and or ethical grounds for consent to be waived).

4. Researchers should always consider children's evolving capacity to **assent** to involvement in the research. The level of assent will depend on the child's age and level of maturity/ level of understanding of the potential risks and benefits of taking part in research.

5. Several guidelines exist which can assist in determining children's readiness for assent and to balance the need to listen to children's wishes with the responsibility to keep them safe. However, it is important to bear in mind that children do not develop at the same rate and thus careful reflection is required. The point of departure is that children assent to participate in research, their ability to decide on risks and benefits varies.

   (i) the Rule of Sevens: suggests children are capable of assent when they become able to understand the research in question and generally this is held to be at age 14. This Rule is based on legal presumption that children under the age of seven cannot be held to have capacity, whilst for a minor aged 14 or older there is presumption of capacity to understand implications of decisions and be held legally accountable. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2588342/

   (ii) Gillick competency: refers to medical advice but often used in a wider context to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4962726/

   (iii) Fraser Guidelines: often applied in the context of advice and treatment relating to contraception and sexual health. https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters/gp-mythbuster-8-gillick-competency-fraser-guidelines

6. Where children participate in clinical research, the following four (4) risk categories are applicable:

   - The research poses **no more than minimal risk** to the child (that is, the risk is commensurate with daily life or routine medical or psychological examinations)
   - The research poses **more than minimal risk** but holds out the prospect of direct benefit for the child participant
   - The research poses a **minor increase over minimal risk**, with no prospect of direct benefit to the child participant, but will likely yield generalisable knowledge about the condition under study
   - The research **does not meet the conditions for the other risk categories** but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

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