

# The advancement of child health caught up in an ethical-legal power play

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## OVERVIEW

- Consensus
- Divergence
- Legal & ethical positions on consent
- Where to from here?



# CONSENSUS

- There is consensus -
  - On public health and human rights importance of child participation in research
  - That uncertainty regarding parental waivers is resulting in researcher frustration, inconsistent REC approaches and inadequate data to address child health needs

## DIVERGENCE

- There is disjuncture between the child consent approaches in the National Health Act (2003) and the national ethics guidelines (2015)
- Differing principles underpinning each approach
  - Law rooted in protection
  - Ethics guidelines rooted in non-discrimination, autonomy and research facilitation

## LEGAL POSITION

- Parent/LG consent required and
- Child consent if “capable of understanding”
- No exceptions

# SOME IMPLICATIONS

- OVC excluded from all health research as they have no parents/LGs and are cared for by “care-givers” who may consent to their medical treatment but not research
- Adolescents reluctant to take part in studies on sensitive topics with parental knowledge/ permission, including:
  - Sexual and reproductive health
  - Sexual identity/ behaviour
  - Illegal or stigmatized behaviours

# ETHICAL POSITION



- Consent from parent/LG and child assent but:
  - Parental consent can be waived in favour of a parental substitute (if the research is with OVC)
  - Parental consent can be waived in favour of a child consenting independently under strict criteria

# ETHICS CRITERIA FOR PARENTAL WAIVERS



Parental substitute	Independent consent
OVC	Desirable & ethically justifiable
Research relevant to OVC	Older participants
OVC must be indispensable	Minimal risk
Risks appropriate	Community support for consent approach
	“Sensitive” research



# WHERE TO FROM HERE?



- RECs need to fulfil their statutory functions in s 73(2) of National Health Act:
  - A. Review research to establish that it will promote health, prevent or cure diseases
  - B. Approve research that meets the ethical standards of the REC

## PROTECTIONS FOR RECs

- To limit their liability if deviating from s71 RECs should:
  - Only approve consent strategies that are consistent with the national ethics guidelines
    - Document the reasons for decisions and deviation from s71
  - Get institutional support for this approach by ensuring research offices are aware of this policy position and its ethical justification

## CONCLUSIONS

- RECS in unenviable position where ethics and law diverge due to a lack of consensus on principles that ought to inform child consent norms

# RECOMMENDATIONS

- RECs should implement ethical approach where REC decisions are ethically justifiable in terms of ethics guidelines and s73 of NHA, even where the approach is inconsistent with s71 of NHA
- RECs should share evolving body of practice about ethically justified parental waivers
- NHREC should provide guidance on how to address this ethical-legal conflict
- Legal department in DOH should implement law reform

## REFERENCES

- Strode, A., Singh, P., Slack, C., & Wassenaar, D. (2018). RECs in a tight spot: Approving consent strategies that are *prima facie* illegal but are ethical in terms of national guidelines. *South African Medical Journal* 108(10):828-832. DOI:10.7196/SAMJ.2018.v108i10.13203.