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

Ann E Strode (PhD)
School of Law, University of KwaZulu-Natal

Catherine M Slack (PhD)
HIV/AIDS Vaccines Ethics Group, UKZN
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
<table>
<thead>
<tr>
<th>Parental substitute</th>
<th>Independent consent</th>
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<tbody>
<tr>
<td>OVC</td>
<td>Desirable &amp; ethically justifiable</td>
</tr>
<tr>
<td>Research relevant to OVC</td>
<td>Older participants</td>
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<td>OVC must be indispensable</td>
<td>Minimal risk</td>
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<tr>
<td>Risks appropriate</td>
<td>Community support for consent approach</td>
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<td>“Sensitive” research</td>
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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 curse 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