

Ethical-legal norms for adolescent HIV prevention trials in South Africa

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Overview of Talk

- Four issues
 - Who should consent to enrolment?
 - Who should give permission for other aspects (contraceptives, testing)?
 - What should researchers do about mandatory reporting for abuse?
 - What should researchers do about mandatory reporting for sexual offenses?
- Guidance in the SA ethical-legal framework
- Recommendations for researchers – navigating tensions

Ethical-legal frameworks for (child) research

- Omissions, ambiguities, contradictions, scattered (UNAIDS 2012) – “imperfect”
- Might not strike right balance between ‘access’ to research & protection
- Challenging for researchers and reviewers so pre-trial ‘audit’ can help
(Slack 2007; UNAIDS 2007; UNAIDS 2012)
- Child = minor = person under 18 in South Africa

1 Consent for Enrolment?

- LAW: Consent from parent/ guardian for child research (s71 NHA 2003 implemented in March 2012)
 - Undermines discretion of RECs to approve other consent approaches
 - Subject of law reform proposal (according to public NHREC-REC meeting)
- ETHICAL GUIDELINES: Consent from parent/ guardian for child research generally:
 - a. Unless other factors e.g. risks are 'minimal', research is 'sensitive', child is older, community support; then self-consent allowable (DoH 2015)
 - b. Unless orphan research, then alternative proxies are allowable (DoH 2015)
 - c. Unless 'exceptional circumstances' 'e.g emergencies'; then care-giver consent allowable (DoH GCP 2006)
- Tension between law (s71, NHA) and guidelines (DoH2015) re. allowable consent approach
- *Recommendation – Secure consent from parent/ LG for trials unless waiver conditions met*

2 Consent for Components (& Privacy)?

- LAW: Various statutes - adolescents can self-consent to health-related interventions, e.g.
 - Contraceptives from 12 (s 134, Children's Act, No. 38 of 2010)
 - HIV testing from 12 (s 130, Children's Act, No. 38 of 2010)
 - Medical treatment from 12, incl. STI / HIV treatment (s 129, Children's Act No. 38 of 2010)
- ETHICAL GUIDELINES: Child research must take into account 'privacy interests' (DoH 2015)
- *Recommendation – even if parent/ LG consents for enrolment:*
 - *Secure self-consent from adolescents for various components*
 - *Ensure they enjoy confidentiality for these components*
 - *Ask adolescents who acquire HIV to disclose to trusted adult in reasonable time-frame*
 - *Set this out in consent materials ('no surprises')*
 - *Allow that some persons may object/ refuse enrolment on these grounds*

3 Mandatory Reporting of Abuse?

- LAW: Abuse and neglect must be reported
 - Broad range of persons (medical practitioners, psychologists, others) must report any child that has been sexually abused, neglected or physically abused (s110 of the Children's Act (2010))
 - To child-protection organizations, social development department, police
- ETHICAL GUIDELINES:
 - Be familiar with obligations (DoH 2015)
 - Ensure abuse and neglect are reported (DoH 2015)
- *Recommendation:*
 - *Partner with professional organizations for assessment and referrals*
 - *Set out limits of confidentiality in consent materials ('deal-breaker')*
 - *Allow that some persons may object/ refuse enrolment when approach is understood*

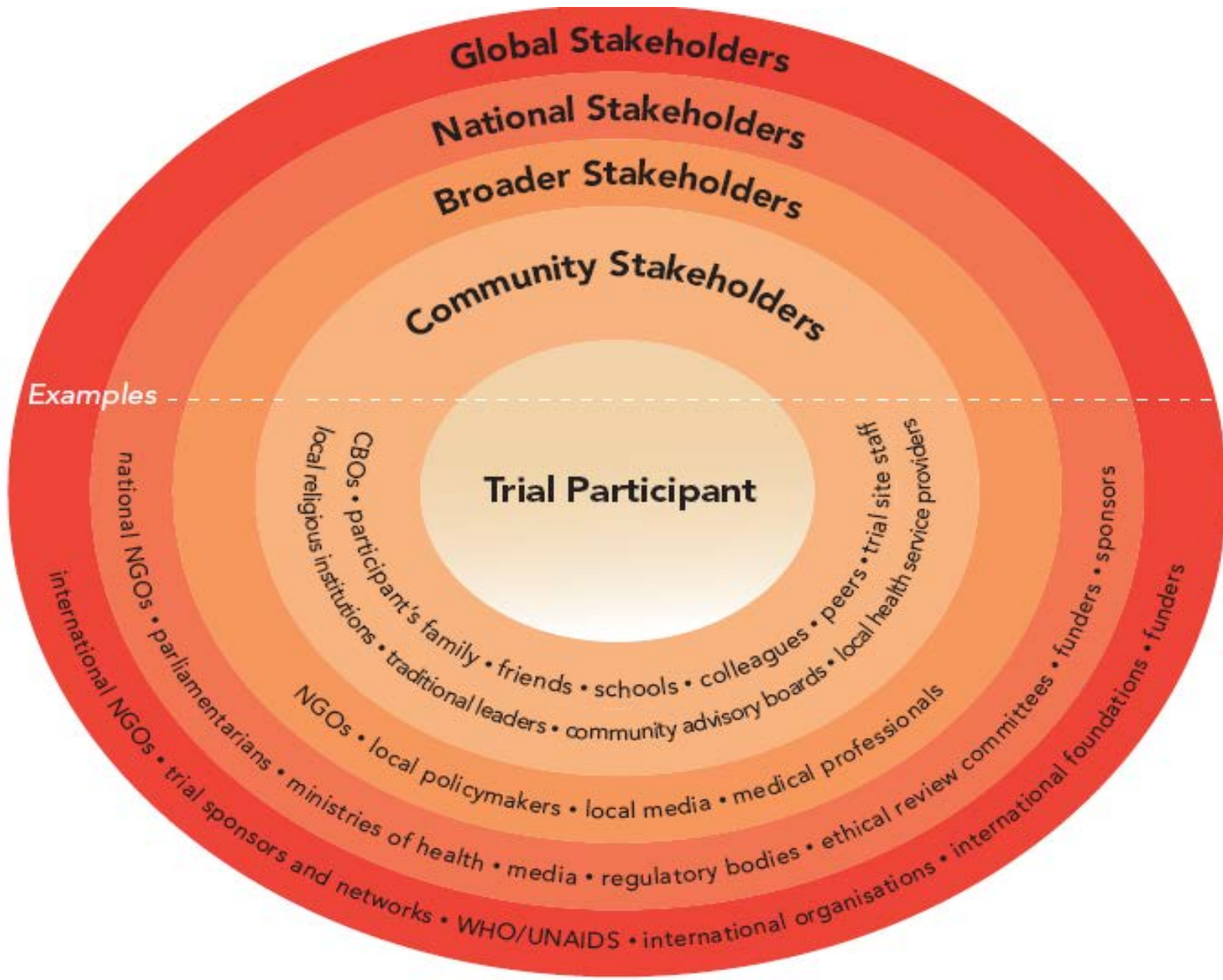
4 Mandatory Reporting of Sexual Offenses?

- LAW: Any person aware of a sexual offence against a child must report to police
(Criminal Law [Sexual Offences and Related Matters] Amendment Act, No. 32 of 2007)
- No longer a reportable offense when adolescents who are peers or 'close-in-age' (2y age gap) engage in sex/sexual activity
 - 12-15yo children with 12-15yo children
 - 12-15yo children with 16-17yo children (if 2year-gap) (Criminal Law (Sexual Offences and Related Matters) Amendment Act Amendment Bill B18B-2014)
- Still a reportable offense when
 - Younger party is 12-15yo *and the older party is 16-17 yo* (+ age difference exceeds 2y)
 - Younger party is 12-15yo *and partner is an adult (18 and over)*
 - Older party commits the 'offense'
- Change in law has relaxed requirements....

4 Cont'd

- ETHICAL GUIDELINES:
 - Caution against 'thoughtless reporting' (DoH 2015)
- *Recommendation:*
 - *Recognize that reporting may cause censorship (undermine prevention services)*
 - *And may drag participants into the CJS (cause social harms)*
 - *Adopt nuanced approach*
 - *Assess carefully - consider coercion, harm*
 - *Partner with experts*
 - *Report only clearly exploitative activity*
 - *Ensure limits understood in consent*
 - *Allow that some persons may object/ refuse enrolment when approach is understood*

UNAIDS AVAC GPP (2011)



Recommendations For Adolescent Researchers

1. Think of the REC as a stakeholder to be engaged
2. Prepare approach carefully - using justifiable norms (see existing resources)
3. Use and cite the most up-to-date ethical guidelines (DoH 2015)
4. Set out the approach for the REC to assess (NIH-CHAMPS studies e.g. PlusPills & EDCTP HPV study)
5. Develop Standard Operating Procedures/ training for site-staff (EDCTP-funded HPV study)
6. Report to REC 'critical ethico-legal events' (frequency, impact, resolution)

**Shift towards protecting children
from unsafe, ineffective interventions
through data from rigorous studies
and shift away from protecting children
*from research participation per se***

(Nelson 2010)

*Building the case
for including adolescents
in ethically sound studies*

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Useful Resources

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Ethics Review

- LAW:
 - RECs must review 'health research' incl. with children – as per s73 of NHA (implemented 2005); regulations (gazetted Sep 2014)
 - RECs must register with NHREC - as per s73 of the NHA
- ETHICAL GUIDELINES:
 - RECs must review 'health research' incl. with children (exemptions allowed) (DoH 2015)
 - RECs must have child expertise (DoH 2015)

Ministerial Consent For NT Child Research

- LAW:
 - MoH required to 'consent' to NTR with children – as per s71(3)(a)(ii) of the National Health Act (NHA)
 - MoH delegated authority to RECs fully registered with NHREC – as per s 92(a) (implemented Oct 2014)
- NHREC OPERATIONAL GUIDELINES:
 - Recommend researchers use Form A in Regulations with Human Participants (published Sep 2014) to show how criteria for ministerial consent are met
 - Recommends RECs review Form A in their ethics reviews
 - <http://www.nhrec.org.za/docs/Documents/OperationalGuidelinesMinisterialConsentFinalFeb2015.pdf>
- ETHICAL GUIDELINES: - recognizes RECs may have been delegated authority and recommends deliberations recorded
- Offsets overly broad wording of Act requiring all NT child research *regardless of risk level* to be reviewed by MoH