

NORMS FOR ADOLESCENT HIV PREVENTION TRIALS

HAVEG www.saavi.org.za/haveg.htm

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The table below sets out proposed ethical-legal standards and norms for adolescent participation in HIV prevention trials in South Africa.

Issue	Law/ Guideline	Proposed standard	Special obligations that should be dealt with in protocol
1. Consent			
Who can consent?	<p><u>Consent to research</u></p> <p>Children become legal majors at 18. Below this age there is currently no express legal guidance on whether adolescents can consent independently to health research. DOH GCP (2000) states that parental consent is required for clinical trials with children in all but exceptional circumstances e.g. emergencies</p> <p>In future, in terms of s71 of the NHA (2003) children will only be able to consent independently to health research at 18</p> <p>NHA (2003) will also require children who have “sufficient understanding” to consent alongside their parent/guardian</p> <p>NHA (2003) will require that consent be in writing.</p> <p><u>Consent to medical treatment</u></p> <p>Children of 14 can consent to medical treatment (Child Care Act, 1983).</p>	<p><i>No independent consent from children under 18</i></p> <p><i>Consent to be obtained from a parent or legal guardian</i></p> <p><i>Children to provide consent alongside their parents if they have understanding</i></p> <p><i>Adolescent research participants should consent independently to: sexual risk assessment, STI testing, HIV testing, terminations of pregnancy (see also privacy section below)</i></p>	<p>Protocol should clarify difference between a caregiver and a guardian and provide that caregivers do not have the legal capacity to consent to children in their care participating in research</p> <p>Protocol should spell out the tools that will be used to assess the understanding of adolescents</p> <p>Protocol should clarify whether adolescents who do not demonstrate enough understanding for “consent” will still be eligible for enrolment</p> <p>Protocol should specify the procedures that children will consent to independently of their parent/guardian</p>
What can be consented to?	<p>Consent may not be contrary to public policy, in other words parents/guardians and adolescents themselves may only consent to research participation if this is legally permissible</p>	<p><i>For procedures that hold out the prospect of direct benefit: risks must be outweighed by the benefit</i></p> <p><i>For procedures that do not hold out the prospect of direct</i></p>	<p>REC to consider which procedures will hold out the prospect of direct benefit, e.g. risk reduction counselling, and if risk-benefit ratio is acceptable</p>

	<p>Consent to research will be contrary to public policy if the risks exceed those specified in national guidelines such as DOH GCP (2000), MRC (2003), NHREC (2004)</p> <p>Consent to research will be contrary to public policy if children under the age of 16 who cannot legally consent to sex are enrolled in an efficacy trial</p>	<p><i>benefit, risks should be commensurate with “daily life” or routine tests, or a minor increase over</i></p> <p><i>Adolescents under the age of 16 should not be enrolled in trials which require sexual activity</i></p>	<p>REC to consider which procedures hold out no prospect of direct benefit (e.g. blood draws) and if risks are reasonable and risk-knowledge ratio is acceptable</p> <p>Protocol to provide data from previous trials that helps RECs to make risk determinations, e.g. data on “behavioural disinhibition”; stigma, false positivity</p> <p>Protocol should spell out risk minimisation measures, e.g. How will increases in risk behaviour be monitored?</p> <p>How will social harms like stigma be monitored?</p> <p>How long will differential testing that can detect a true HIV infection be provided for? ID card? Hotline for complaints?</p>
2. Privacy			
<p>What adolescent information will be kept private from their parents/legal guardians?</p>	<p>Law says that every person has the right to privacy. However the individual must have a subjective expectation of privacy that is regarded as reasonable by the community</p> <p>Individuals may be asked to waive their privacy rights in some circumstances</p>	<p><i>Information on sexual risk assessment, terminations of pregnancy, STIs diagnosis and treatment should be kept confidential</i></p> <p><i>HIV test results should be disclosed to parents/guardians within a reasonable time frame</i></p>	<p>Protocol should stipulate the information that will not be disclosed to parents</p> <p>Protocol should specify the social support that will be given to adolescents for Sexually Transmitted Infections, terminations of pregnancy, etc</p> <p>Protocol should specify that adolescents will be required to disclose to a trusted adult that they are HIV positive within 3 months of being tested</p>
3. Child protection laws			
<p>In what circumstances must vulnerable children be reported to the authorities?</p>	<p>The Child Care Act (1983) requires medical practitioners to report ill-treatment, abuse and neglect to DSD. Family Violence Act (1992) requires any person who attends to children who suspects ill-treatment must report to social worker/ police.</p> <p>In the future the Children’s Act (2005) will oblige any person who identifies a child in need of care and protection to report this to a social worker.</p> <p>SA Schools Act (1996) provides that children are</p>	<p><i>Children that disclose to trial site staff that they are being abused, neglected, or ill-treated must be assisted.</i></p>	<p>Protocol must state how child reporting laws will be complied with.</p> <p>In instances where abuse, neglect or ill-treatment is suspected, trial site staff could ask Child-Line to make a comprehensive assessment.</p>

	required to attend school between the ages of 7 and 15. There is no legal obligation to attend school after this age but it would be in the best interests of children to remain at school until they have completed matric	<i>Trial participation should not interfere with school work</i>	Trials ensure that clinic hours are outside of core school hours
4. Procedural obligations			
What special procedural obligations exist regarding child research participants?	The NHA (2003) says that once s 71 is operationalised, ministerial consent must be obtained for all NTR with minors	<i>Ministerial consent must be obtained once this is a legal requirement</i>	Protocol should deal with: <ul style="list-style-type: none"> • Scientific necessity of the research • How it will benefit minor-participants directly or minors as a class • How the research is not contrary to public policy (i.e. meet acceptable risk standards)
5. Other			
Access to treatment for HIV infection	MRC (2003) asserts that trial participants who become infected during the trial will have access to high quality care and treatment including ART.	<i>Adolescents who sero-convert should have access to treatment including ART</i>	Protocol must spell out how treatment will be ensured for adolescents, including ART when it is required. Will national roll-out be relied upon? If it cannot provide appropriate coverage, what alternatives mechanisms are in place?
Access to prevention services	The most appropriate risk-reduction counselling and access to state of the art preventive methods should be provided to trial participants for the duration of the trial, with new methods being added as they are discovered and validated, or approved by relevant authorities (MRC, 2003; UNAIDS, 2007).	<i>All enrolled adolescents should receive comprehensive risk-reduction counselling and methods to decrease the risk of HIV infection, adding new methods to the package of prevention as they are proven effective.</i>	The protocol should specify : <ul style="list-style-type: none"> • what prevention services will be offered to adolescents • whether these services will be provided free of charge or at a cost to participants • whether counselling services will be provided by trial staff or by an independent body • processes for monitoring risk-reduction interventions
Payment	Participants should receive reimbursement for travel and compensation for time and inconvenience (MRC, 2003); participants should be reimbursed for costs (DOH GCP, 2000).	<i>All participants should receive compensation for time/inconvenience and their direct expenses should be reimbursed.</i>	RECs should approve all payments to participants.