For minors (persons under 18) to benefit from scientific advances, it is essential to enroll them in research. Norms in the South African ethical-legal framework are not always harmonized, therefore researchers and RECs working with adolescents (persons 12-17) may find the following recommendations helpful.

RECOMMENDATION 1 ADOLESCENTS SHOULD ONLY BE ENROLLED IN SOCIALLY VALUABLE RESEARCH THAT POSES ACCEPTABLE RISKS

i. National ethics guidance (SA DOH 2015) states that studies with minors should investigate a ‘problem of relevance’ to them and their participation should be ‘scientifically indispensable’.

ii. Guidelines (SA DOH 2015) and regulations (SA DOH 2014) state that minors should participate in research that:
   o Poses/involves no more than minimal risk of harm
   o Poses/involves more/greater than minimal risk but holds out/provides the prospect of direct benefit for the minor. The degree of risk of harm should be justified by the potential benefit; or
   o Poses/involves greater than minimal risk of harm, with no prospect of direct benefit to the minor, but is anticipated to yield/ has a high probability of generalizable knowledge. The risk of harm should be justified by the risk-knowledge ratio. Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.

iii. Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research is not greater than (commensurate with) that ordinarily encountered ‘in daily life in a stable society or in routine medical, dental, educational or psychological tests or examinations’ (SA DOH 2014; SA DOH 2015).
RECOMMENDED APPROACH

1. The scientific justification for enrolment of adolescents must be spelled out in the study protocol.
2. Study components that hold out the prospect of benefit should be spelled out in the protocol, so RECs can assess if a ‘risk-benefit’ ratio is met.
3. Study components that do not hold out the prospect of direct benefit should also be spelled out, so RECs can determine if a ‘risk-knowledge’ ratio is met.

RECOMMENDATION 2 PARENTS OR GUARDIANS SHOULD GENERALLY PROVIDE CONSENT FOR ADOLESCENT ENROLMENT, UNLESS A WAIVER CAN BE ETHICALLY JUSTIFIED

i. The law (s71 of the National Health Act) permits only parents/legal guardians to consent for enrolment of under-18s, whereas the national guidelines permit parental waivers in some instances – allowing a broader range of consent approaches (Strode, 2015; Slack 2016).

ii. More specifically, in some instances alternative proxies are permitted to consent when parents or legal guardians are not available. That is, national clinical trial guidelines permit parental substitutes in the form of caregivers as defined in s1 of the Children’s Act 2005 to consent to clinical trials when enrolling orphans without court-appointed guardians (SA DOH GCP 2020). National ethics guidelines also allow caregiver consent for health research when enrolling ‘orphans’ or ‘vulnerable’ children (SA DOH 2015). Caregivers are generally adults (i.e. ‘a foster parent, the person at the ‘head’ of a child ‘centre’ or ‘shelter’, a child worker). However a ‘child at the head of a child-headed household’ who is 16 and older is also defined as a ‘caregiver’, and in this latter instance we recommend that RECs should consider how these proxy consenters’ vulnerabilities will be offset if consent is to be sought from them.

iii. Also national ethics guidelines permit, in some instances, a self-consent approach - namely where the research is ‘sensitive’; the risks are ‘minimal’; and the child is ‘older’ i.e. 16. It is also relevant whether community stakeholders support the approach (SA DOH 2015).

RECOMMENDED APPROACH

1. The consent strategy should be justified in the protocol.
2. Generally, a parental/guardianship consent approach to adolescent enrolment should be adopted, unless waivers can be justified based on criteria in national ethics guidance (DOH 2015).
3. Where parental consent will not be waived, researchers should seek the consent of the biological or adoptive parent of a child or another person appointed by the high court or nominated in a will (Slack 2011) and the assent of the adolescent.
4. Where parental consent will be waived in favour of a care-giver consent approach, RECs should evaluate whether adolescents meet the definition of ‘vulnerable’ or ‘orphaned’, and whether ‘caregivers’ to be approached fit the definition in the Children’s Act and will be appropriately
supported. Also, RECs should decide whether to exercise discretion afforded to RECs by national ethics guidance (DOH 2015) to approve this approach (Strode 2018).

5. Where parental consent will be waived in favour of self-consent, RECs should evaluate whether conditions for this approach set out in national ethics guidance (DOH 2015) have been met (namely ‘sensitive’ research with ‘minimal risk’ involving ‘older’ adolescents) and decide whether to approve such approaches in accordance with ethics guidance (Strode 2018).

6. In all instances, study staff may benefit from a Standard Operating Procedure to help them implement the chosen consent approach.

7. In all instances, adolescent participants should access materials and strategies that optimize their informed, voluntary decision-making regarding participation (SA DOH 2015).

**RECOMMENDATION 3 ADOLESCENT PARTICIPANTS SHOULD SELF CONSENT TO RELEVANT COMPONENTS, EVEN WHERE PROXY CONSENT IS OBTAINED FOR ENROLMENT, AND ENJOY CONFIDENTIALITY FOR THIS**

According to various statutes, adolescents can consent independently to various health-related interventions (Strode 2010, 2011, 2017), such as:

i. **HIV testing** from age 12 (s 130, Children’s Act, 2010) and under-12s can consent independently if they have ‘sufficient capacity’.

ii. **Medical treatment** from age 12, including for STIs and HIV, provided ‘sufficient maturity’ exists, namely mental capacity to understand the benefits, risks, social and other implications of the treatment (s 129, Children’s Act, 2010).

iii. **Surgical operations** at age 12 provided ‘sufficient maturity’ exists, namely mental capacity to understand the benefits, risks, social and other implications of the surgical operation’ and assistance by a parent or guardian. (s129(3) of the Children’s Act, 2005).

iv. **Circumcision** at age 16 with prior counselling (s12 (8) and s12(9 -10) of the Children’s Act, 2005) For under 16s, consent must be obtained from a parent/ legal guardian; be justified by ‘religious’ or ‘medical reasons on the recommendation of a medical practitioner’.

v. **Contraceptives** and contraceptive advice, including emergency contraceptives from age 12 (s 134, Children’s Act, 2010).

vi. **Terminations of Pregnancy** at any age (s 5, Choice of Termination of Pregnancy Act, 1996). However providers must advise minors to ‘consult with their parents, guardian, family members or friends’ before the termination (s 5, Choice of Termination of Pregnancy Act).

**RECOMMENDED APPROACH**

1. Adolescent participants should give their own consent for HIV or STI testing from age 12 if they have ‘sufficient capacity’/ ‘maturity’ (Strode 2010, 2011, 2017).

2. Adolescent participants needing male or female condoms, other contraceptives or advice should receive these on their own from the age of 12 (Strode 2010, 2011, 2017).

3. Adolescent participants should give their own consent for pregnancy tests from the age of 12 and could receive a TOP at any age with their own consent (Strode 2010, 2011, 2017).
4. In all instances, adolescent participants should be reminded that - while they have the right to self-consent to various interventions - adolescents can and should involve trusted adults for support including parents where adolescents endorse this.

5. Adolescent participants should be linked to appropriate service organizations by researchers, who should form an early and sustained partnership with such organizations.

6. Adolescent participants should enjoy confidentiality for the range of health-related interventions to which they have consented independently, which means the results should go to them directly (and not to parents if a parental consent approach is to be used).

RECOMMENDATION 4 ADOLESCENT PARTICIPANTS SHOULD ENJOY CONFIDENTIALITY FOR RISK BEHAVIOUR, EVEN WHERE PROXY CONSENT IS OBTAINED

i. Minors have a right to privacy if there is an expectation of privacy that society regards as reasonable. Where the law is silent on whether a right to privacy exists, one can use the ‘legitimate expectation test’ to establish if something should be kept private.

ii. Adolescents can lawfully engage in sex at age 16 (Sexual Offences Act (s 15, Criminal Law (Sexual Offences and Related Matters) Amendment Act 2007).

RECOMMENDED APPROACH

1. Adolescent participants who are 16 years and older should enjoy confidentiality for their sexual risk data, and directly receive the results of sexual risk assessments (and not their parents if a parental consent strategy is adopted). This is because older adolescents would have an expectation of privacy which most would hold as reasonable, because adolescents can lawfully consent to sex at 16.

2. Adolescents participants who are between the age of 12 and 15 should receive the same approach, because consensual sex within their peer group is no longer a sexual offence (See Recommendation 7).

3. Adolescent participants should be encouraged to seek support from trusted adults - including parents where appropriate – to reduce their risk.

4. Adolescent participants should be enabled to access risk-reduction services, and researchers should partner with relevant organizations where necessary.

RECOMMENDATION 5 ADOLESCENT PARTICIPANTS SHOULD BE ENCOURAGED TO OBTAIN SUPPORT THROUGH THE DISCLOSURE OF OTHERWISE CONFIDENTIAL INFORMATION TO TRUSTED ADULTS IN CERTAIN INSTANCES

i. A child’s right to confidentiality regarding their health status can be limited where this is in their “best interests” (s 13(1)(d) Children’s Act 2005) – which involves various factors promoting a child’s physical, moral, emotional and spiritual welfare to be evaluated, weighed and balanced. The child’s wishes must be taken into account.

ii. Respect for emerging autonomy can be balanced by the need to minimize harms and promote welfare, as set out in ethics guidance.
RECOMMENDED APPROACH

1. Adolescent participants who acquire conditions with long-term complications, that need ongoing support, should be asked to disclose to a trusted adult (which may constitute their parent should they so wish) within a reasonable time-frame, because this is in their best interests.

2. For example, maintaining confidentiality regarding a child’s HIV status or pregnancy may not be in their best interests as these conditions require long-term emotional support.

RECOMMENDATION 6 IF ADOLESCENT PARTICIPANTS ARE BEING ABUSED OR NEGLECTED THIS SHOULD BE REPORTED TO AUTHORITIES AND ADOLESCENTS SHOULD BE ASSISTED

i. A broad range of persons must report any child that has been sexually abused, deliberately neglected or abused in a manner causing physical injury. These include medical practitioners, nurses, psychologists, social service professionals, social workers and members of staff or volunteer workers at drop-in centres or child and youth care centres (s110 of the Children’s Act 2010).

ii. Any person who, on reasonable grounds, believes that a child is in need of care and protection may report that belief.

iii. Reports are to be made to designated child protection organizations, the provincial department of social development or police officials.

RECOMMENDED APPROACH

1. Study staff should engage key stakeholders such as child protection organizations to secure expertise in making determinations about abuse or neglect, and to provide services to affected adolescents.

2. Study staff may benefit from an SOP for mandatory reporting.

3. Adolescent participants should be encouraged to reach out for support, including reaching out to their parents, where this is appropriate.

RECOMMENDATION 7 IF ADOLESCENT PARTICIPANTS ARE ENGAGED IN UNDERAGE CONSENSUAL SEXUAL RELATIONSHIPS THAT ARE EXPLOITATIVE, THIS SHOULD BE REPORTED TO AUTHORITIES AND ADOLESCENTS SHOULD BE ASSISTED

i. Any person who is aware of a sexual offence having been committed against a child must report this to the South African Police Service (SAPS) (The Criminal Law [Sexual Offences and Related Matters] Amendment Act 2007).

ii. Reportable sexual offences include:

   a. All instances of commercial sex work and rape (including all sex with persons under 12, even if ‘consensual’).
b. Where 16 -17 year olds have sex/ sexual activity with 12-15 year-olds if there is more than a 2 year age gap between them.

c. Where persons older than 18 have sex/sexual activity with a child between the ages of 12 – 15 years even if consensual.

iii. We recommend a more nuanced approach to b. and c.

RECOMMENDED APPROACH

1. In terms of (iia) all instances of commercial sex work and rape identified in adolescent participants should be reported to SAPS.

2. In terms of (iib), when an older adolescent participant (16/17) reports that they are sexually involved with a younger person and more than a 2 year age gap exists, researchers should not necessarily report the participant unless the sex/activity is deemed to be exploitative; based on a careful assessment of criteria such as coercion, with input from child protection experts.

3. In terms of (iib) when younger adolescent participants (12-15) report they are sexually involved with older adolescents (with more than a 2 year age gap) researchers should not necessarily report the partner unless the same can be met.

4. This approach may increase the honesty with which risk-behaviour is reported, enable tailored risk-reduction services, ensure that harmful exploitative activities are reported, and avoid social harms to participants brought into the Criminal Justice System as the offender or the victim.

5. In terms of (iiic) when adolescent participants between 12 and 15 years report consensual sexual activity with an adult (18 and over) the study team should be aware that this is the crime of ‘statutory rape’. However the study team should assess each incident on a case by case basis, with inputs from experts in child protection. For example, when an adolescent participant of 15 reports consensual sex with an 18 year old, this should be assessed differently to when a 15 year old reports consensual sex with a 30 year old. The over-riding principle should be the best interests of the child.

6. In terms of (iiic) when adolescent participants between 16 and 17 years report consensual sexual activity with an adult (18 and over) the study team should be aware that this is not the crime of ‘statutory rape’ because adolescents can consent to sex at 16. However, depending on the nature of the relationships, such reports may represent abuse in terms of the Children’s Act e.g. where an adolescent participant of 16 years reports sexual activity with a 25 year old teacher (See Recommendation 6).

RECOMMENDATION 8 IF ADOLESCENT PARTICIPANTS DISCLOSE OTHER ‘OFFENSES’ THIS SHOULD NOT BE REPORTED TO AUTHORITIES AND ADOLESCENTS SHOULD BE ASSISTED

i. Where adolescents are acting in a way that contravenes other laws, there may be no legal obligation to report this. But there is an ethical responsibility to assist.

ii. All children between the ages of 7 and 15 must attend school (the South African Schools Act 1996).

iii. It is illegal for children under the age of 15 to work, or those between the ages of 15 and 18 to perform unsuitable work (work that places their well-being, education, physical or
mental health, or spiritual, moral or social development at risk) (the Basic Conditions of Employment Act 1997).

RECOMMENDED APPROACH

1. Adolescent participants who report *truancy* should not be reported to an authority, because this is not required by law. However, researchers may wish to encourage under-15s to disclose truancy to their parents, where appropriate, so that parents can act to fulfil their duty, and researchers should refer adolescents for assistance, and ensure that study visits do not interfere with school attendance.

2. Adolescent participants who report *child labour* or inappropriate work should not be reported to an authority, because this is not required by law. However, researchers should act in the minor’s best interests and refer them to appropriate expertise.

3. Adolescent participants who have committed or are committing *crimes* (e.g. abusing substances, committing theft) should not be reported to authorities, as this is not required by law. Where adolescents are being exploited by an adult (e.g. where a child is being forced to sell drugs by an adult) reporting is required by law because this amounts to “ill treatment”. However, researchers should consider whether the social harms to participants (e.g. of repercussions from adult criminals) outweigh the legal duty to report such ill-treatment, and engage child protection experts to inform decisions.

4. Adolescents may inform researchers of a *third party* who has been the “victim” of a crime or has “committed” a crime. There is no legal duty to report this to an authority, however researchers should take steps to help where such a person is in clear and imminent danger, e.g. consult child protection experts with whom they have partnered.

5. Child protection and service organizations should be engaged early by the study team.

6. Adolescents experiencing such problems should be encouraged to reach out for forms of adult support, including their parents where this seems helpful.

RECOMMENDATION 9 THE CONSENTING PARTY (PARTIES) SHOULD UNDERSTAND WHAT INFORMATION WILL BE DISCLOSED TO PROXY CONSENTORS OR TO AUTHORITIES

The consenting party (or consenting parties) should understand what information about the enrolled adolescent will be kept confidential and what will be disclosed to another party.

RECOMMENDED APPROACH

1. Consent materials and discussions should clarify that – even where a parental consent approach is adopted – parents will not be informed by the study team about adolescents’ medical tests (HIV and STIs and pregnancy), contraception and risk-behaviour. However, adolescents will be encouraged to make their own disclosures to trusted persons to secure support, which might include parents.

2. Consent materials and discussions should clarify that certain categories of sexual activity will be reported to authorities e.g. rape and commercial sex work, as well as underage consensual sex deemed to be ‘exploitative’.

3. Enrolment may be declined when such approaches are understood.
RECOMMENDATION 10 STAKEHOLDERS THAT REPRESENT THE INTERESTS OF ADOLESCENTS SHOULD BE ENGAGED BY ADOLESCENT RESEARCHERS IN AN EARLY AND SUSTAINED MANNER

‘Researchers should engage key role players at various stages of planning and conducting research to improve the quality and rigour of the research, to increase its acceptability to the key role players, (and) to harness role player expertise where possible’ (SA DOH 2015).

RECOMMENDED APPROACH

1. Relevant adolescent service organizations should be identified and partnered with.
2. This will enable researchers to make determinations about abuse, neglect or exploitative sexual relations in collaboration with expert partners, and enable adolescents to access appropriate services.

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LAWS AND ETHICS GUIDELINES

- Section 71 of the National Health Act No. 61 of 2003.
- Section 5 of the Choice on Termination of Pregnancy Act No. 92 of 1996.
- Section 130 of the Children’s Act No. 38 of 2005.
- Section 129 of the Children’s Act No. 38 of 2005.
- Section 134 of the Children’s Act No. 38 of 2005.
- Section 12(8) and section 12(9-10) of the Children’s Act No. 38 of 2005.
- Section 110 of the Children’s Act 38 of 2007.
- Section 15 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act No, 32 of 2007.
- South African Schools Act No. 84 of 1996.
- The Basic Conditions of Employment Act No.75 of 1997.

ARTICLES


