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The ethical-legal requirements for adolescent self-consent to research in sub-Saharan Africa: A scoping review

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Abstract

Support for the enrolment of adolescents in research has been constrained by uncertainties in parental involvement, and the lack of clarity in the ethical and legal frameworks. We conducted a scoping review to examine articles that explored the opinion of scholars on the question of adolescent consent and conditions for parental waivers in research in sub-Saharan Africa (SSA). Guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) tool, we searched electronic databases (PubMed, EMBASSE, EBSCOHOST) and also reviewed the references of articles identified for additional relevant literature. We included full text English articles focusing on adolescent consent and parental waivers in SSA that were published between 2004 and 2020. We excluded studies focusing on healthcare, theses, and reviews. We reviewed a total of 21 publications from South Africa (n = 12), Kenya (n = 4) and Botswana, Malawi, Nigeria, Uganda and Zimbabwe (n = 1 each). We identified four broad thematic issues: the current position regarding parental waivers and self-consent; parental involvement in the consent process; the role of community approval or consent when adolescent self-consent approaches were used; and complexities and ambiguities in legal requirements and ethical guidelines on adolescent consent. Our findings show inconsistencies and ambiguities in the existing legal and ethical frameworks within and across different countries, and underscore the need for consistent and clearer guidance on parental waivers and adolescent self-consent. Harmonization of the legal and ethical frameworks taking into account varying contexts is critically important to ensure research on adolescents in SSA meets adolescents' specific unmet needs.

KEYWORDS

adolescent self-consent, ethical-legal guidelines, parental waiver, sub-Saharan Africa

1 | BACKGROUND

Adolescents are a vulnerable group that merit special protection under the law and in international ethical guidelines when they are eligible to be enrolled as research participants. Parental consent and adolescent assent are used as a standard mechanism to protect minor adolescents in research-related decision-making processes. In many countries, the age of majority (18) is the age of consent to research participation and in certain situations, they allow waivers of parental consent for emancipated minors.[1] The blanket requirement of parental consent for all research involving minors has been widely criticized. Concerns include failure to recognize children's capacities and accord children due respect as persons in their own right, risks of disclosing sensitive information to the parents, and potential conflicts between protecting and violating adolescents' autonomy.[2] Guidelines issued by the Council for International Organisations of Medical Sciences (2016) try to address this by allowing for a waiver of parental consent and grant adolescent self-consent where the risk level is minimal, and where special protections are put in place to ensure the protection of the minor's best interest.[3] However, ethical and legal frameworks that determine whether adolescents can consent independently to research are inconsistent or absent.[4] Consequently, the guidelines are interpreted differently in different places, and uncertainties remain over how to ensure waivers of parental consent and adolescent self-consent can be applied consistently.

We conducted a scoping review of peer-reviewed studies to identify conditions and opinions for adolescent self-consent and parental waivers in research in sub-Saharan Africa (SSA).

[1]Bauman, L. J., Mellins, C. A., & Klitzman, R. (2020). Whether to waive parental permission in HIV prevention research among adolescents: Ethical and legal considerations. *The Journal of Law, Medicine & Ethics*, *48*(1), 188–201. Day, S., Kapogiannis, B. G., Shah, S. K., Wilson, E. C., Ruel, T. D., Conserve D. F, Strode, A., Donenberg, G. R., Kohler, P., Slack, C., Ezechi, O., Tucker, J. D., & PATC3H Consortium Adolescent Bioethics Working Group. (2020). Adolescent participation in HIV research: Consortium experience in low and middle-income countries and scoping review. *Lancet HIV*, *7*(12), e844–e852. https://doi.org/10.1016/S2352-3018(20)30269-1; Schenk, K. D., Friedland, B. A., Chau, M., Stoner, M., Plagianos, G., Skoler-Karpoff, S., Palanee, T., Ahmed, K., Rathlagana, M. J. M., Mthembu, P. N., & Ngcozela, N. (2014). Enrollment of adolescents aged 16-17 years old in microbicide trials: An evidence-based approach. *Journal of Adolescent Health*, *54(6)*, 654–662. Council for International Organisations of Medical Sciences (CIOMS). (2016). International ethical guidelines for health-related research involving humans. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

[2]Dwyer-Lindgren, L., Cork, M. A., Sligar, A., Steuben, K. M., Wilson, K. F., Provost, N. R, Mayala, B. K., VanderHeide, J. D., Collison, M. L., Hall, J. B., Biehl, M. H., Carter, A., Frank, T., Douwes-Schultz, D., Burstein, R., Casey, C. D. D., Deshpande, A., Earl, L., El Bcheraoui, C., … Ha, S. I. (2017). Mapping HIV prevalence in sub-Saharan Africa between 2000 and 2017. *Nature*, *570*, 189–209. https://doi.org/10.1038/s41586-019-1200-9

[3]World Health Organization, UNAIDS & United Nations Children's Fund (UNICEF) (2011). Global HIV/AIDS response: Epidemic update and health sector progress towards Universal Access: Progress report 2011. World Health Organization. https://apps.who.int/iris/handle/10665/44787

[4]Zanoni, B. C., Archary, M., Buchan, S., Katz, I. T., & Haberer, J. E. (2016). Systematic review and meta-analysis of the adolescent HIV continuum of care in South Africa: The cresting wave. *BMJ Global Health*, *1*(3), 1–9. Vreeman, R., & Kamanda, A. (2013). Community perspectives on research consent involving vulnerable children in Western Kenya. *The Journal of Empirical Research on Human Research Ethics*, *7*(4), 44–55. Embleton, L., Ott, M. A., Wachira, J., Naanyu, V., Kamanda, A., Makori, D., Ayuku, D., & Braitstein, P. (2015). Adapting ethical guidelines for adolescent health research to street-connected children and youth in low- and middle-income countries: A case study from western Kenya. *BMC Medical Ethics*, *16*, 1–11. https://doi.org/10.1186/s12910-015-0084

2 | METHODS

We conducted the scoping review from September 2019 to March 2020 using a two stage process. We were interested in articles that explored the opinion of scholars on the question of adolescent consent and conditions for parental waivers in research, in SSA. In the first stage, we searched electronic databases (PubMed, EMBASSE, EBSCOHOST) to identify peer reviewed studies. We then reviewed the references of these articles for additional relevant literature that might have been missed through the initial search. The search terms included 'consent' AND 'assent'; 'self-consent'; AND 'adolescent research'; AND 'parental waiver'; 'sub-Saharan Africa', 'community approval'; 'ethical-legal guidelines and adolescent research'.

2.1 | Inclusion criteria

We considered 18 years as the legal age for consent, and we included articles focusing on issues of parental waivers, and adolescent consent in research. We included full text English articles published between January 1, 2004 and March 31, 2020. This period was of particular interest because this was a time of rapid increase in adolescent HIV prevention, clinical trials, pre-exposure prophylaxis, treatment as prevention and antiretroviral therapy in sub-Saharan countries.[5] We also included articles providing expert opinion on the landscape and mapping of the ethical and legal guidelines.

2.2 | Exclusion criteria

Studies focusing on adolescents' research outside of adolescent consent and parental waivers such as healthcare provision, knowledge, attitudes and practices studies were excluded. Studies focusing on infants, or youth above 18 years were excluded. However, we included studies with participants in the age range 15-20 years as the focus was on consent and parental waivers. We also excluded studies from North America, Europe, Asia, and the Middle East, as well as non-primary literature including commentaries, theses and reviews.

2.3 | Study selection

We use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) tool to guide the selection process. The initial search resulted in a total of 2,118 articles from the electronic search and 16 from references from selected articles. Records initially identified through the search were screened to exclude studies that were unrelated to the research topic. After irrelevant studies were excluded, the remaining literature was screened further (abstracts) by authors B. N. and B. Z. to determine applicability according to inclusion and exclusion criteria. The

[5]Dwyer-Lindgren et al., op. cit. note 2, p. 4; World Health Organization, op. cit. note 3; Zanoni et al., op. cit. note 4.

studies were screened independently, and later as a team. Differences and discrepancies were resolved by discussions until a consensus was reached. Following this level of screening, the remaining 92 articles were considered for a full text screening using the same strategy to identify a final list of papers meeting the study criteria. Out of 92 studies screened for full text, 71 were excluded because the articles included non-primary literature (n = 9); the population was either infants or above 18 years old (n = 8); were not from SSA (n = 28); and the focus did not involve adolescent self-consent, parental waiver, or parental consent/adolescent assent (n = 26) (see Figure 1).

3 | DATA ANALYSIS

Using a matrix (word document) B. N. and B. Z. categorized articles meeting the criteria into four main themes, (a) the current position regarding parental waivers and self-consent approaches; (b) parental involvement in the consent process; (c) the role of community approval or consent when adolescent self-consent approaches were used; and (d) and complexities and ambiguities in legal requirements and ethical guidelines on adolescent consent (see Table 1). Studies addressing more than one theme were charted in one category using a consensus approach.

4 | RESULTS

We identified a total of 21 studies, including those from South Africa (n = 12); Kenya (n = 4) and Botswana, Malawi, Nigeria, Uganda and Zimbabwe (n = 1 each). The studies included: social science studies; willingness to participate (WTP) studies; simulated clinical trials; intervention programmes focusing on parental waivers and adolescent consent; as well as articles on the ethical and legal guidelines surrounding adolescent participation and parental waivers /parental consent.

5 | THE CURRENT POSITION REGARDING PARENTAL WAIVERS AND SELF-CONSENT APPROACHES

Studies reviewed showed that there are no objective or biological markers to define when or what age an individual becomes an adult and at what age they have the actual capacity to give consent. We found that there is variability in when adolescents are permitted to self-consent and what conditions make it ethically acceptable. Kenya, Nigeria and Uganda granted parental waivers for emancipated minors including orphans and married adolescents. Furthermore, Kenya made provisions for children experiencing substance abuse and those

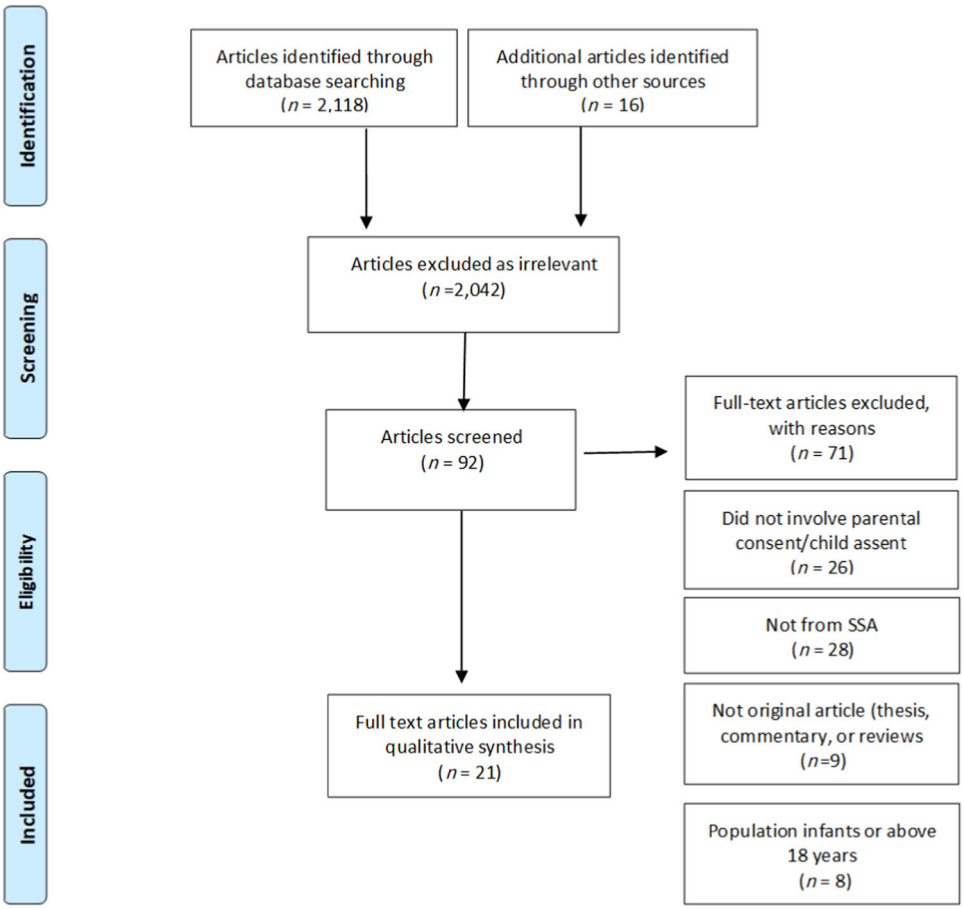

FIGURE 1 PRISMA flow diagram

TABLE 1 List of studies and thematic domains

Date of publication	Journal title	Author	Title	Country	Methodological approach
The current position regarding parental waivers and self-consent approaches					
2006	PLoS Medicine 3(7): 984-988	Singh et al.	Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa	South Africa	HIV clinical trial
2012	J Acquir Immune Defic Syndr 58(2): 211-218	Otwombe et al.	Willingness to participate in biomedical HIV prevention studies after the HVTN 503/Phambili trial: A survey conducted amongst adolescents in Soweto, South Africa	South Africa	Quantitative survey
2013	Journal of Empirical Research 7(4): 44-55	Vreeman and Kamanda	Community perspectives on research consent involving vulnerable children in Western Kenya	Kenya	Qualitative study
2014	J AIDS HIV Res 4(2): 30-35	Adler	Inclusion of South African adolescents in HIV vaccine trials	South Africa	Qualitative study
2015	BMC Medical Ethics 16(89): 1-11	Embleton et al.	Adapting ethical guidelines for adolescent health research to street-connected children and youth in low- and middle-income countries: A case study from western Kenya	Kenya	Qualitative study
Parental involvement in the consent process					
2007	BMC Medical Ethics 8(5): 1-8	Slack et al.	Enrolling adolescents in HIV vaccine trials: Reflections on legal complexities from South Africa	South Africa	Reflections paper
2012	BMC International Health and Human Rights 12(1): 1-5	Zuch et al.	Changes to the law on consent in South Africa: Implications for school-based adolescent sexual and reproductive health research	South Africa	Reflections paper
2013	Journal of Empirical Research 7(4): 44-55	Vreeman and Kamanda	Community perspectives on research consent involving vulnerable children in Western Kenya	Kenya	Qualitative study
2015	BMC Medical Ethics 16(89): 1-11	Embleton et al.	Adapting ethical guidelines for adolescent health research to street-connected children and youth in low- and middle-income countries: A case study from western Kenya	Kenya	Qualitative study
2016	African Journal of AIDS Research 15(1): 9-15	Vig and Miller	Involving parents from the start: Formative evaluation for a large RCT with Botswana Junior Secondary School students	Botswana	Qualitative study
2016	South African Journal of Bioethics Law 9(2): 78-83	Worku et al.	A critical review of health research ethical guidelines regarding caregiver consent for HIV research involving minors in South Africa: Ethical and legal issues	South Africa	Reflections paper
2018	African Journal of AIDS Research 17(3): 227-239	Groves et al.	"I think the parent should be there because no one was born alone": Kenyan adolescents' perspectives on parental involvement in HIV research	Kenya	Qualitative study
2018	Ethics & Behav. 25(2): 169-179	Thokoane	Ethical challenges for piloting sexual health programs for youth in Hammanskraal, South Africa: Bridging the gap between rights and services	South Africa	Sexual and reproductive health (SRH) intervention programme

TABLE 1 (Continued)

Date of publication	Journal title	Author	Title	Country	Methodological approach
2018	South African Medical Journal 108(4): 291-298	Wallace et al.	Feasibility and acceptability of conducting HIV vaccine trials in adolescents in South Africa: Going beyond willingness to participate towards implementation	South Africa	Simulated HIV clinical trial
2019	BMC Medical Ethics 20(32): 1-13	Mangochi et al.	How should assent to research be sought in low income settings? Perspectives from parents and children in Southern Malawi	Malawi	Qualitative study
2019	BMC Medical Ethics 20(41): 1-16	Marsh et al.	Who should decide about children's and adolescents' participation in health research? The views of children and adults in rural Kenya	Kenya	Qualitative study
The role of community approval or consent when adolescent self-consent approaches are used					
2005	American Journal of Public Health 95(7): 1266-1269	Mathews et al.	Written parental consent in school-based HIV/AIDS prevention research	South Africa	Qualitative study
2006	PLoS Medicine 3(7): 984-988	Singh et al.	Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa	South Africa	HIV clinical trial
2009	Vaccine 26(45): 5679–5683	Jaspan et al.	Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa	South Africa	Qualitative study
2012	BMC Medical Ethics 13(17): 1-5	Bwakura-Dangarembizi et al.	Ethical and legal constraints to children's participation in research in Zimbabwe: Experiences from the multicenter paediatric HIV ARROW trial	Zimbabwe	Reflections paper
2012	BMC Medical Ethics 23(13): 1-11	Vreeman et al.	A qualitative study using traditional community assemblies to investigate community perspectives on informed consent and research participation in Western Kenya	Kenya	Qualitative study
2012	BMC International Health and Human Rights 12(1): 1-5	Zuch et al.	Changes to the law on consent in South Africa: Implications for school-based adolescent sexual and reproductive health research	South Africa	Reflections paper
2013	Journal of Empirical Research 7(4): 44-55	Vreeman and Kamanda	Community perspectives on research consent involving vulnerable children in Western Kenya	Kenya	Qualitative study
2014	J AIDS HIV Res 4(2): 30–35	Adler	Inclusion of South African adolescents in HIV vaccine trials	South Africa	Qualitative study
2015	Pan African Medical Journal 22(76): 1-7	Buregyeya et al.	Motivations and concerns about adolescent tuberculosis vaccine trial participation in rural Uganda: A qualitative study	Uganda	Qualitative study
2015	Developing World Bioethics 15(13): 191-198	Folayan et al.	Ethical issues in adolescents sexual and reproductive health research in Nigeria	Nigeria	Reflections paper
2015	BMC Medical Ethics 16(89): 1-11	Embleton et al.	Adapting ethical guidelines for adolescent health research to street-connected children and youth in low- and middle-income countries: A case study from western Kenya	Kenya	Qualitative study

(Continues)

TABLE 1 (Continued)

Date of publication	Journal title	Author	Title	Country	Methodological approach
2018	African Journal of AIDS Research 17(3): 227-239	Groves et al.	"I think the parent should be there because no one was born alone": Kenyan adolescents' perspectives on parental involvement in HIV research	Kenya	Qualitative study
2018	Ethics & Behav. 25(2): 169-179	Thokoane	Ethical challenges for piloting sexual health programs for youth in Hammanskraal, South Africa: Bridging the gap between rights and services	South Africa	Sexual and reproductive health (SRH) intervention programme
2019	BMC Medical Ethics 20(41): 1-16	Marsh et al.	Who should decide about children's and adolescents' participation in health research? The views of children and adults in rural Kenya	Kenya	Qualitative study
Complexities and ambiguities in legal requirements and ethical guidelines					
2006	PLoS Medicine 3(7): 984-988	Singh et al.	Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa	South Africa	HIV clinical trial
2007	BMC Medical Ethics 8(5): 1-8	Slack et al.	Enrolling adolescents in HIV vaccine trials: Reflections on legal complexities from South Africa	South Africa	Reflections paper
2008	Journal Assoc Nurses AIDS Care 18(2): 78–82	MacQueen and Karim	Adolescents and HIV clinical trials: Ethics, culture, and context	South Africa	Clinical trial
2012	BMC International Health and Human Rights 12(1): 1-5	Zuch et al.	Changes to the law on consent in South Africa: Implications for school-based adolescent sexual and reproductive health research	South Africa	Review of ethical and legal guidelines
2014	J AIDS HIV Res 4(2): 30–35	Adler	Inclusion of South African adolescents in HIV vaccine trials	South Africa	Qualitative study
2014	Journal of the International AIDS Society 17(1): 19075	Karim and Dellar	Inclusion of adolescent girls in HIV prevention research – An imperative for an AIDS-free generation	South Africa	Reflections paper
2014	South African Journal of Bioethics and Law 15(2): 46-49	Strode et al.	Failing the vulnerable: Three new consent norms that will undermine health research with children	South Africa	Reflections paper
2016	African Journal of AIDS Research 15(1): 9–15	Vig and Miller	Involving parents from the start: Formative evaluation for a large RCT with Botswana Junior Secondary School students	Botswana	Qualitative study
2016	South African Journal of Bioethics Law 9(2):78-83	Worku et al.	A critical review of health research ethical guidelines regarding caregiver consent for HIV research involving minors in South Africa: Ethical and legal issues.	South Africa	Reflections paper
2018	Ethics & Behav. 25(2): 169–179	Thokoane	Ethical challenges for piloting sexual health programs for youth in Hammanskraal, South Africa: Bridging the gap between rights and services	South Africa	Sexual and reproductive health (SRH) intervention programme
2019	BMC Medical Ethics 20(32): 1-13	Mangochi et al.	How should assent to research be sought in low income settings? Perspectives from parents and children in Southern Malawi	Malawi	Qualitative study

TABLE 2 Legal and ethical framework for adolescent informed consent and conditions for waiver of parental consent

Country	Legal and ethical framework for adolescent informed consent	Conditions for waivers of parental consent
Botswana	Age of consent is 18 years	No guidelines for parental waivers. However, there are guidelines for parental waivers for accessing sexual health reproductive services (SRHS).
Kenya	Parental or guardian consent and adolescent (age 12–18 years) assent to participate in research is required. Parental or guardian consent can be waived for emancipated adolescents (i.e. adolescents granted legal adult status by court order) or mature adolescents (i.e. who are married, pregnant mothers, or household head).	National guidelines for doing adolescent HIV or sexual health research also outline circumstances when a waiver of parental or guardian consent might be appropriate, such as if the child is a member of a key population (e.g. LGBT, MSM, sex workers, or people who use drugs).
Malawi	Assent to participate in a study must be obtained from minors who are capable of providing assent. In determining whether children are capable of assenting, National Health Science Research Committee (NHSRC) shall take into account the ages, maturity and psychological state of the children involved. However, minors must assent in tandem with parental permission. In certain cases, NHSRC may regard assent by minors to represent an informed consent. Typical case is when such minors are emancipated. These emancipated minors may include those that society may regard as mature minors; that are legally married; or university students under a defined Malawian adult age of 18 years.	There are no guidelines for parental waivers in research.
Nigeria	No clear legislation exists specifically stating the minimum age of consent for research participation in Nigeria because of contradictions in the existing legal frameworks. The age at which an individual can consent differs between legislative acts, variously defining age 18 years (1999 Constitution of the Federal Republic of Nigeria), age 16 years (2003 Child Right Act), and age 14 years (1958 Children and Young Persons Act) as the age of independent consent.	National guidelines established in 2014 recommend that individuals age 16 years and older (in therapeutic research) or 13 years and older (in non-therapeutic research) be allowed to provide independent consent. These guidelines also waive parental consent for individuals younger than 16 years who are married, a head of household, emancipated, or experiencing abuse perpetrated by their parent or guardian.
South Africa	The National Health Act requires parental or guardian consent for the participation of individuals younger than 18 years and the adolescent's assent. However, national ethical guidelines developed by the Department of Health include provisions for waiving parental or guardian permission for individuals younger than 18 years in various circumstances; for instance, if the risks are minimal, the child is older than 16 years, researchers provided evidence of engagement with participating community members to show a waiver of parental permission is acceptable, and an REC approved the waiver	Parental or guardian consent can be waived if participants are 16 years and older; the study poses minimum risks; it is a 'sensitive study'; and there is community approval of consent strategy if parental consent is undesirable and the adolescents will be self-consenting
Uganda	Individuals younger than 18 years require parental or guardian consent and adolescent assent to participate in research.	A mature or emancipated minor can consent independently to research participation under these conditions: (a) the institutional REC approves the research study on the basis of community evidence; (b) the protocol provides clear justification for involvement of mature or emancipated minors. Mature minors are defined as individuals age 14–17 years who have drug dependency or an STI. Emancipated minors are defined as individuals younger than 18 years who are pregnant, married, have a child, or are financially self-sufficient.
Zimbabwe	Age of consent is 18. Individuals younger than 18 years require parental or guardian consent and adolescent assent to participate in research.	No guidelines for parental waivers.

Source: Day et al. (2020). See note 1.

who are homeless. In South Africa, conditions for parental waivers included the sensitive nature of the study, older adolescents, 16 and older, minimum risks and community consent. There was no data on parental waivers in Botswana, Malawi and Zimbabwe (see Table 2). We identified two Kenyan studies, where parental consent was waived and an adolescent self-consent approach was used.[6] The studies involved hard to reach adolescents including orphans and vulnerable children and children living on the streets between the ages of 10–19 years. The researchers obtained community approval through consultations with the local leaders, and professionals including teachers, and social workers, working closely with the ethics committee to obtain a waiver of parental consent. The ethics committee found that the self-consent approach would not adversely alter the risk-benefit ratio for participants. The self-consent approach was justified on the basis that the studies could not have been carried out without the parental waiver. Involving this cohort was essential to the study objectives to identify adolescent health needs and broader challenges they face in the community.

We also found that a study involving an HIV vaccine trial in South Africa did not get approval from the ethics committee. The investigators set out to employ a self-consent strategy by including adolescents 14 years or older.[7] Adolescents were to be recruited from pre-natal and family planning clinics without seeking parental consent. Consequently, the researchers had to change the age range of participants to those above 18 because the study posed more than minimal risk. Most of the clinical studies in this scoping review were WTP or HIV clinical simulation studies, which may reflect the difficulties in obtaining parental waivers, particularly for higher risk or interventional research.[8]

6 | PARENTAL INVOLVEMENT IN THE CONSENT PROCESS

We found divergent views regarding the level of parental involvement in adolescent participation in research. These views were based on the type of study and potential to breach adolescent confidentiality, as well as adolescent–parent relationships. Our findings showed a growing recognition that adolescent research participation should be a joint decision-making process between the parents, or caregivers and the adolescents.[9] This joint approach strengthens understanding of the study because both parties (parents or caregivers and adolescents) receive the same information, regardless of the consent approach. The role of parents in these instances is seen as the providing of support for their children.[10]

A WTP study in South Africa showed that although adolescents reported that parents should provide consent for adolescent participation in vaccine trials, they expressed concern about a lack of control over access to their study results.[11] Studies on adolescents' views about parental consent in Kenya showed heterogeneity across youth and their preferences regarding parental consent.[12] Adolescents supported parental consent and their protective role as a safeguard in case something went wrong during the study and from community gossip about their involvement in the research study.

A randomized controlled trial (RCT) examining the efficacy of a behavioural intervention targeting adolescent sexual risk behaviours in Botswana, reported that adolescents were likely to report pressure from parents or relatives, and that younger adolescents aged 13–15 were likely to refuse.[13] In this study, parents who provided consent for their adolescents during the RCT had mixed reactions when informed that they would not have access to a participant's results unless their children voluntarily shared the information with them or voluntarily involved them in the return of results process. Ultimately, the desire of parents to be involved and to access their children's HSV-2 results overrode the importance of protecting the confidentiality of the adolescents, breaching the adolescents' privacy. In the South African WTP study some participants were of the view that adolescents should have the autonomy to enrol without parental consent.[14] Their rationale was that parental consent may prevent some adolescents from study participation if the parent was not readily available to give consent or refused.

7 | THE ROLE OF COMMUNITY APPROVAL OR CONSENT WHEN ADOLESCENT SELF-CONSENT APPROACHES WERE USED

We found that community approval of an adolescent-self consent strategy is an ethical norm unique to the South African framework.[15] Although this was not a requirement in Kenya, we found two studies that used community consent and were granted a parental waiver by the ethics committee.[16] The studies

[6]Vreeman & Kamanda, op. cit. note 4; Embleton et al., op. cit. note 4.

[7]Schenk et al., op. cit. note 1.

[8]Singh, J. A., Karim, S. S. A., Karim, Q. A., Mlisana, K., Williamson, C., Gray, C., Govender, M., & Gray, A. (2006). Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa. *PLoS Medicine, 3*(7), 984–988.

[9]World Health Organization, op. cit. note 3; Worku, E. B., Davis, A. M., & Morrow, B. (2016). A critical review of health research ethical guidelines regarding caregiver consent for HIV research involving minors in South Africa: Ethical and legal issues. *South African Journal of Bioethics and Law, 9*(2), 78–83; Vig, J., & Miller, K. S. (2016). Involving parents from the start: Formative evaluation for a large RCT with Botswana Junior Secondary School students. *African Journal of AIDS Research, 15*(1), 9–15; Vreeman, R., Kamaara, E., Kamanda, A., Ayuku, D., Nyandiko, W., Atwoli, L., Ayaya, S., Gisore, P., & Braitstein, P. (2012). A qualitative study using traditional community assemblies to investigate community perspectives on informed consent and research participation in western Kenya. *BMC Medical Ethics, 13*(23), 1-11; Buregyeya, E., Kulane, A., Kiguli, J., Musoke, P., Mayanja, H., & Mitchell, E. (2015). Motivations and concerns about adolescent tuberculosis vaccine trial participation in rural Uganda: A qualitative study. *Pan African Medical Journal, 8688*, 1–7; Strode, A., Richter, M., Wallace, M., Toohey, J., & Technau, K. (2014). Failing the vulnerable: Three new consent norms that will undermine health research with children. *South African Journal of Bioethics and Law, 15*(2), 46–49; Foloyan, M. O., Haire, B., Harrison, A., Odetoyingbo, M., Fatusi, O., & Brown, B. (2015). Ethical issues in adolescents sexual and reproductive health research in Nigeria. *Developing World Bioethics, 15*, 191–198; Slack, C., Strode, A., Fleischer, T., Gray, G., & Ranchod, C. (2007). Enrolling adolescents in HIV vaccine trials: Reflections on legal complexities from South Africa. *BMC Medical Ethics, 8*(5), 1–8.

[10]World Health Organization, op. cit. note 3, p. 5; Worku et al., op. cit. note 9; Foloyan et al., op. cit. note 9.

[11]Adler, D. H. (2014). Inclusion of South African adolescents in HIV vaccine trials. *Journal of AIDS and HIV Research, 4*(2), 30–35.

[12]Buregyeya et al., op. cit. note 9; Foloyan et al., op. cit. note 9.

[13]Vig & Miller, op. cit. note 9.

[14]Adler, op. cit. note 11.

[15]Vreeman et al., op. cit. note 9.

involved adolescents living on the street and orphaned children, and parental consent could not be obtained. We also found that there are no guidelines or definition for community approval when using the self-consent strategy. In the two studies in Kenya, community approval was obtained through consultations with the local leaders, and professionals including teachers, and social workers.

In most of the studies reviewed, community consultation was key in respecting and gaining access to the community, and adolescents.[17] The communities' input was used to improve the informed consent process such as clarifying study materials and strengthening referral linkages in clinical trials.[18] Community consent was therefore viewed as an appropriate and necessary strategy even before individual consent to extend protections from the individual to the community-level, and was considered as a potential alternative to parental consent in cases where parental consent was not feasible, or when the child is not well cared for.[19]

A study in Nigeria showed that culture rather than the law carries greater weight. This was evidenced in the importance of consultations within the more immediate family circle. In this study it was reported that some parents wanted to talk with their families or respected people in their community before reaching a decision about providing consent for an adolescent to participate in a sexual and reproductive health research, especially when such research involves invasive procedures such as regular blood draws and vaginal examinations.[20] This approach is in line with the view of other authors who argue that ethical guidelines that focus on parental involvement specifically for the purpose of enrolling an adolescent minor into a study fail to consider that adolescents are embedded in relationships with partners, peers, families and communities.[21]

None of the authors defined the scope or breadth of community consultations. However, a study from Kenya cautioned against reliance on community leaders as this might marginalize individuals and groups who may not feel able to speak freely in group deliberations, and thus their opinions may go unheard in community discussions.[22]

8 | COMPLEXITIES AND AMBIGUITIES IN LEGAL REQUIREMENTS AND ETHICAL GUIDELINES ON ADOLESCENT CONSENT

Most of the authors argued that existing ethical and legal norms act as a barrier in enrolling adolescents in clinical trials.[23] The divergent approaches to consent taken in law and ethical guidelines add a layer to these complexities (Table 2). In South Africa, the divergent consent approaches in ethical and legal frameworks present challenges regarding enrolment of adolescents in clinical trials.[24] The legal guidelines (National Health Act 2003) limit parental consent to biological or parents and legal guardians, potentially excluding children who do not have biological parents or legal guardians. This contradicts the ethical guidelines, which allow for alternative adults including caregivers, and other parental figures.[25] Furthermore, the National Health Act (2003) contradicts the Children's Act, which recognizes children's rights to privacy and the evolving capacity of children to consent to a range of health interventions without parental consent.

Similar contradictions were reported in Nigeria's Child Rights Act and the National Health Research Ethics Code (NHREC) of 2011.[26] The Child Rights Act provides that a child who has attained the age of 16 years has the right to give consent for scientific investigation without parental consent, while the ethical research code is not explicit about the age of consent. Furthermore, the legal requirement for parental consent poses challenges as most adolescents live with surrogate caregivers. Therefore, ethics committees act based on their discretion informed by the NHREC.[27] In Kenya, the Ethical Conduct of Biomedical Research Involving Human Subjects allows for a parent or

[16]Dwyer-Lindgren et al., op. cit. note 2; World Health Organization, op. cit. note 3.

[17]Embleton et al., op. cit. note 4; Singh et al., op. cit. note 8; Thokoane, C. (2018). Ethical challenges for piloting sexual health programs for youth in Hammanskraal, South Africa: Bridging the gap between rights and services. *Ethics & Behavior, 25*(2), 169–179; Worku et al., op. cit. note 9; Vreeman et al., op. cit. note 9; Zuch, M., Mason-Jones, A. J., Mathews, C., & Henley, L. (2012). Changes to the law on consent in South Africa: Implications for school-based adolescent sexual and reproductive health research. *BMC International Health and Human Rights*, *12*(1), 1-5; Bwakura-Dangarembizi, M., Musesengwa, R., Nathoo, K. J., & Takaidza, P. (2012). Ethical and legal constraints to children's participation in research in Zimbabwe: Experiences from the multicenter pediatric HIV ARROW trial. *BMC Medical Ethics*, *13*(17), 1-5; Buregyeya et al., op. cit. note 9; Marsh, V., Mwangome, N., Jao, I., Wright, K., Molyneux, S., & Davies, A. (2019). Who should decide about children's and adolescents' participation in health research? The views of children and adults in rural Kenya. *BMC Medical Ethics*, 20 (14), 1–16; Mathews, C., Guttmacher, S. J., Flisher, A. J., Mtshizana, Y., Hani, A., & Zwarenstein, M. (2005). Written parental consent in school-based HIV/AIDS prevention research. *American Journal of Public Health*, *95*(7), 1266–1269; Groves, A. K., Hallfors, D. D., Iritani, B. J., Rennie, S., Fredrick, S., Kwaro, D, Amek, N., & Luseno W. K. (2018). "I think the parent should be there because no one was born alone": Kenyan adolescents' perspectives on parental involvement in HIV research. *African Journal of AIDS Research, 1-13*; Jaspan, H. B., Soka, N. F, Strode, A. E., Mathews, C., Mark, D., Flisher, A., Wood, R., & Bekker, L. (2009). Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa. *Vaccine*, *26*(45), 5679–5683.

[18]Zanoni et al., op. cit. note 4; Worku et al., op. cit. note 9.

[19]Slack et al., op. cit. note 9.

[20]Buregyeya et al., op. cit. note 9.

[21]Worku et al., op. cit. note 9; Mangochi, H., Gooding, K., Bennett, A., Parker, M., Desmond, N., & Bull, S. (2019). How should assent to research be sought in low income settings? Perspectives from parents and children in Southern Malawi. *BMC Medical Ethics, 20(32)*, 1–13; Slack et al., op. cit. note 9.

[22]Vreeman & Kamanda, op. cit. note 4.

[23]Bauman et al., op. cit. note 1; Day et al., op. cit. note 1; Wallace, M., Middelkoop, K., Smith, P., Bennie, T., Chandia, J., Churchyard, G., Gray, G., Latka, M. H., Mathebula, M., Nchabeleng, M., Roux, S., Slack, C., Strode, A., & Bekker, L.-G. (2018). Feasibility and acceptability of conducting HIV vaccine trials in adolescents in South Africa: Going beyond willingness to participate towards implementation. *South African Medical Journal*, *108*(4), 291–298; Buregyeya et al., op. cit. note 9; Marsh et al., op. cit. note 17; Mathews et al., op. cit. note 17; Strode et al., op. cit. note 9; Adler, op. cit. note 11; Karim, Q. A., & Dellar, R (2014). Inclusion of adolescent girls in HIV prevention research – An imperative for an AIDS-free generation. *Journal of the International AIDS Society, 17*, 1–2.

[24]Bauman et al., op. cit. note 1; Schenk et al., op. cit. note 1. Council for International Organisations of Medical Sciences, op. cit. note 1. Vreeman et al., op. cit. note 9; Marsh et al., op. cit. note 17; Alexander, A. B., Ott, M. A., Lally, M. A., Sniecinski, K., Baker, A., & Zimet, G. D. (2015). Adolescent decision making about participation in a hypothetical HIV vaccine trial. *Vaccine*, *33*(11), 1331–1337; Otwombe, K. N., Sikkema, K. J., Dietrich, J., Bruyn, G., van der Watt, M., & Gray, G. (2012). Willingness to participate in biomedical HIV prevention studies after the HVTN 503/Phambili trial: A survey conducted amongst adolescents in Soweto, South Africa. *Journal of Acquired Immune Deficiency Syndromes*, *58*, 211–218.

[25]Wallace et al., op. cit. note 23.

[26]Foloyan et al., op. cit. note 9.

[27]Ibid.

legal guardian to give proxy consent despite the reality that many adolescents do not live with biological or legal guardians. While there no specific laws that are dedicated to research involving children in Zimbabwe, the Medicines and Allied Substances Control Act requires that the parent or legally authorized representative provide consent on behalf of a minor.[28]

Key problems within these frameworks include the use of age as a proxy for maturity. Most authors argued that age is not always an appropriate proxy for adolescent self-consent and authors advocated that researchers and ethics committees should look at maturity, or mental capacity; and or use competency tests[29] to take into account the evolving maturity of adolescents, and subsequent participation in research. However, findings from a study in Kenya showed that some of the adolescent participants felt that adolescents 16 years and over were capable of making their own decisions about research participation, therefore should be granted parental waiver.[30]

We did not find clarity on the issue of assent from adolescents. A study in Malawi reported the difficulties and the lack of clarity and guidance regarding age at which assent and consent should be sought.[31] The authors highlighted the diverse household structures and adolescents' living arrangements including children living in boarding schools, or adolescents living on their own as a result of educational and employment opportunities. In this context, obtaining parental consent becomes difficult.

9 | DISCUSSION

Our review shows wide support for adolescents' participation in research; however, there are mixed views about the level of parental involvement in decision-making regarding research participation. Four broad thematic issues emerged. First, delineating the role of parents in the consent process during adolescent research[32] and finding the balance between the protective function of parental consent and its potential to act as a barrier to research.[33] The absence of objective or biological markers to define when an individual becomes an adult and at what age they have the actual capacity to give consent underscores the importance for the field of bioethics to pay greater attention to adolescents. Second, if parental consent is to be waived, it is not clear under which circumstances this would be ethical and what ought to be the procedural obligations that should be met.[34] The study risk level was often found to influence the granting of parental waivers. This is demonstrated in the HIV vaccine efficacy trial in South Africa in which parental waivers were not granted because the risk level was more than minimal.[35] Studies posing more than minimal risk, such as the South African clinical trial, used WTP due to the inability to obtain parental waivers. While WTP studies inform future recruitment and retention efforts, they are not a good predictor of future successful recruitment and retention of adolescents into HIV vaccine trials.[36] In Kenya, the parental waiver was granted in two exploratory studies where the risk level was minimal and parental consent was not feasible.[37] Third, support for wider community engagement and consultation as a protective mechanism for adolescent participation, and the lack of guidance on community consent, resulted in synonymous use with community participation. Fourth, there are inconsistencies and ambiguities in the existing legal and ethical frameworks within and across different countries.[38]

Our study highlights gaps and ambiguities in national ethical and legal frameworks regarding adolescent participation in research. The authors in most of the papers argued that parental consent has the potential to act as a barrier in research involving sensitive topics such as sexual orientation, SRH research and HIV prevention studies.[39] This was demonstrated in the RCT study in Botswana, where the desire of parents to be involved and to access their children's HSV-2 results overrode the importance of protecting the confidentiality of the adolescents, breaching the adolescents' privacy.[40]

We also found that cultural values play a major role in decision-making as shown by family and community participation in decision-making in many SSA countries.[41] Several scholars discussed the role of community consultations. Several argued that consultation and engagement of the community prior to research protocol submission to the ethics committee creates the opportunity to discuss the rationale underpinning the inclusion of adolescents in the research, and waivers of parental consent in studies where such is a requirement.[42] Community endorsement of research plans is perceived as being a major factor in research ethics committee considerations on whether to allow adolescents to provide autonomous consent for participation in a study.[43]

Although our study focused on the SSA region, complexities in legal and ethical frameworks, which take different approaches regarding the autonomous participation of adolescents in research, have been reported

[28]Bwakura-Dangarembizi et al., op. cit. note 17.
[29]Buregyeya et al., op. cit. note 9.
[30]Ibid.
[31]Strode et al., op. cit. note 9.
[32]Thokoane, op. cit. note 17. Vig & Miller, op. cit. note 9; Marsh et al., op. cit. note 17; Groves et al., op. cit. note 17. Mangochi et al., op. cit. note 21.
[33]Thokoane, op. cit. note 17; Worku et al., op. cit. note 9; Zuch et al., op. cit. note 17; Foloyan et al., op. cit. note 9;; Slack et al., op. cit. note 9; Adler, op. cit. note 11; Jaspan et al., op. cit. note 17.
[34]Embleton et al., op. cit. note 4; Singh et al., op. cit. note 8; Thokoane, op. cit. note 17;, Vreeman et al., op. cit. note 9; Mathews et al. op. cit. note 17.
[35]Zanoni et al., op. cit. note 4.
[36]Alexander et al., op. cit. note 24; Otwombe et al., op. cit. note 24.
[37]Dwyer-Lindgren et al., op. cit. note 2; World Health Organization, op. cit. note 3.
[38]Singh et al., op. cit. note 8; Thokoane, op. cit. note 17; Zuch et al., op. cit. note 17; Karim & Dellar, op. cit. note 23; Strode, A., & Slack, C. (2005). Ethical and legal challenges in enrolling adolescents in medical research in South Africa: Implications for HIV vaccine trials. *South African Journal of Science, 101*, 223–228; MacQueen, K., & Karim, Q. (2008). Adolescents and HIV clinical trials: Ethics, culture, and context. *Journal of the Association of Nurses in AIDS Care, 18*(2), 78–82.
[39]Zanoni et al., op. cit. note 4;Vreeman & Kamanda, op. cit. note 4; Vig & Miller, op. cit. note 9.
[40]Vig & Miller, op. cit. note 9.
[41]Dwyer-Lindgren et al., op. cit. note 2. World Health Organization, op. cit. note 3; Vreeman & Kamanda, op. cit. note 4; Buregyeya et al., op. cit. note 9.
[42]Vig & Miller, op. cit. note 9.
[43]Day et al., op. cit. note 1; Marsh et al., op. cit. note 17.

in other places including North America and the United Kingdom.[44] While most studies from the SSA region underscore broader community engagement and consultation, such consultation is limited to the parents or immediate family in North America.

International research guidance increasingly supports the proactive inclusion of children and adolescents in health research in recognition of the need for more evidence-based treatment. This is reinforced by international agencies including the Global Strategy for Women's, Children's and Adolescents' Health of the United Nations, and the Global Accelerated Action for the Health of Adolescents of the World Health Organisation, and the Global Accelerated Action for the Health of Adolescents of the World Health Organization.[45] Despite the growing interest and divergent views surrounding parental waivers, and adolescent self-consent in SSA, our study showed that there is limited research involving prospective adolescent HIV research participants in SSA.[46]

10 | STRENGTHS AND LIMITATIONS

This comprehensive review highlights differing approaches in adolescent participation, as well as emerging trends including broader community engagement in addition to parental consent in SSA.

It is possible that our search did not detect all publications that covered issues relevant to adolescent research ethics, for example, due to inclusion only of studies conducted in English. By excluding studies from North America, we may have inadvertently omitted information from studies that included data about SSA. Although the majority of the studies propose community engagement and consultation, defining these concepts was beyond the scope of this review.

11 | CONCLUSION

Our findings show a complexity and variance in how adolescents are included in research without parental permission and underscore the need for consistent and unambiguous guidance on parental waivers and adolescent self-consent. Harmonization of the legal and ethical guidelines taking into account varying contexts is critically important to ensure research on adolescents in SSA meets their specific unmet needs.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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