

# ETHICAL ISSUES IN ADOLESCENTS' SEXUAL AND REPRODUCTIVE HEALTH RESEARCH IN NIGERIA

MORENIKE OLUWATOYIN FOLAYAN, BRIDGET HAIRE, ABIGAIL HARRISON, MOROLAKE ODETOYINGBO, OLAWUNMI FATUSI AND BRANDON BROWN

## Keywords

Africa,  
research ethics,  
informed consent

## ABSTRACT

There is increasing interest in the need to address the ethical dilemmas related to the engagement of adolescents in sexual and reproductive health (SRH) research. Research projects, including those that address issues related to STIs and HIV, adverse pregnancy outcomes, violence, and mental health, must be designed and implemented to address the needs of adolescents.

Decisions on when an individual has adequate capacity to give consent for research most commonly use age as a surrogate rather than directly assessing capacity to understand the issues and make an informed decision on whether to participate in research or not. There is a perception that adolescents participating in research are more likely to be coerced and may therefore not fully comprehend the risk they may be taking when engaging in research.

This paper examines the various ethical issues that may impact stakeholders' decision making when considering engaging adolescents in SRH research in Nigeria. It makes a case for lowering the age of consent for adolescents. While some experts believe it is possible to extrapolate relevant information from adult research, studies on ethical aspects of adolescents' participation in research are still needed, especially in the field of sexual and reproductive health where there are often differences in knowledge, attitudes and practices compared to adults. The particular challenges of applying the fundamental principles of research ethics to adolescent research, especially research about sex and sexuality, will only become clear if more studies are conducted.

## INTRODUCTION

Adolescents are individuals between childhood and adulthood who are in the process of reaching physical, psychological and sexual maturity. The Nigerian adolescent health policy recognises the adolescent age range as the second decade of life, 10 to 19 years<sup>1</sup> in line with the definition by the World Health Organization.<sup>2</sup> Adoles-

cents represent one fifth of the world's population but constitutes a larger proportion of the population of low and middle income countries (LMIC) compared to developed countries due to the demographic transition.<sup>3</sup> Individuals aged 10 to 19 years constitute 11% of the population in high income countries, 18.1% of middle income countries, and 23% of low income countries.

<sup>1</sup> Federal Ministry of Health, Nigeria. National Adolescent Health Policy. 1996.

<sup>2</sup> WHO. 10 facts on adolescent health. 2008. Available at: [http://www.who.int/features/factfiles/adolescent\\_health/en/index.html](http://www.who.int/features/factfiles/adolescent_health/en/index.html). [Accessed 20 March 2014].

<sup>3</sup> UNICEF. Progress for Children: A report card on adolescents, Number 10, April 2012. Available at: [http://www.unicef.org/media/files/PFC2012\\_A\\_report\\_card\\_on\\_adolescents.pdf](http://www.unicef.org/media/files/PFC2012_A_report_card_on_adolescents.pdf) [Accessed 20 March 2014].

Address for correspondence: Morenike Oluwatoyin Folayan, Obafemi Awolowo University, Child Dental Health, Faculty of Dentistry, Ile-Ife, Osun State 22005 Nigeria. Email: [toyinukpong@gmail.com](mailto:toyinukpong@gmail.com).

Conflict of interest statement: No conflicts declared

1 The Nigerian population is young with well over 55% of  
2 the population below 29yrs.<sup>4</sup> There is therefore the need to  
3 pay particular attention to the health needs of this popu-  
4 lation. The data on age of sexual initiation and rates of  
5 sexual violence make it clear that more adolescent-specific  
6 research needs to be conducted to construct an evidence  
7 base for the planning and implementing adolescent-  
8 specific sexual and reproductive health programmes in  
9 Nigeria. Data cannot be extrapolated from older popula-  
10 tions because adolescent experiences are specific to their  
11 societal context, shaped by factors including gender expect-  
12 ations and the socialisation processes at family levels.<sup>5</sup>  
13 Development of guidelines that would support and  
14 promote the conduct of ethically valid research among  
15 adolescents in Nigeria is therefore essential.

16 It is worth noting that adolescence is a combination of  
17 physical, psychological and social changes that manifest  
18 differently in different cultural settings. Therefore, it is  
19 crucial to consider each adolescent as a reference unit  
20 when developing, planning and implementing pro-  
21 grammes related to their needs.

22 There are several justifications for conducting research  
23 on adolescents' SRH. These include the need to under-  
24 stand the determinants of specific patterns of sexual  
25 behavior and practices, predictors and age of onset of  
26 sexual activity, the life-long impact of sexual behavior on  
27 adolescents' physical and psychological health, and the  
28 health and psycho-social needs that results from these  
29 issues.

30 One rationale for conducting biomedical or socio-  
31 behavioural research is that it may lead to discovery of  
32 information that could guide the delivery of appropriate  
33 preventive and therapeutic services. Therefore, research  
34 on adolescents' reproductive health can lead to develop-  
35 ment of interventions that may maximize adolescents'  
36 health. The omission of adolescent focused research per-  
37 petuates inadequate understanding of their particular  
38 reproductive health needs.

39 The Nigerian constitution considers a person under 18  
40 years a minor with limited legal capacity. This minor in  
41 most situations requires a legally authorized surrogate  
42 decision maker (parent, guardian or family member) to  
43 act on their behalf.<sup>6</sup> However, The Child Rights Act<sup>7</sup>  
44 provides that a child who has attained the age of 16 years  
45 has the right to give consent for scientific investigation  
46 without parental consent. In practice, adolescents aged  
47

48 <sup>4</sup> National Population Commission [Nigeria]. National Demographic  
49 Health Survey 2003, 2008.

50 <sup>5</sup> A.O. Fatusi & M.J. Hindin. Adolescents and youth in developing  
51 countries: Health and development issues in context. *Journal of Adoles-*  
52 *cence* 2010; 33: 499–508.

53 <sup>6</sup> Federal Government of Nigeria. Constitution of the Federal Republic  
54 of Nigeria. 1999.

55 <sup>7</sup> Federal Ministry of Women Affair, Nigeria. Convention on the right  
56 of the child. Second country report. 2004.

15 years and older are regularly engaged in national  
surveys on HIV prevalence.<sup>8</sup>

In this paper, we will consider whether the need for  
more information about adolescent SRH justifies the  
lowering of the legal age of consent in Nigeria. In making  
this assessment, we will consider the level of demon-  
strated need for evidence-based SRH programs for  
younger adolescents. We discuss issues of capacity, coer-  
cion, and risk assessment in and by younger adolescents  
and whether extrapolation of findings from other popu-  
lations is adequate.

## SEXUAL AND REPRODUCTIVE HEALTH NEEDS OF ADOLESCENTS IN NIGERIA

A large number of adolescents initiate sex early. The  
median age of sexual debut being 16 years for girls and 17  
years for boys.<sup>9</sup> Studies have shown only 10.5% of ado-  
lescents in Nigeria use contraceptives, including  
condoms, perhaps, partly due to lack of detailed knowl-  
edge about the use of different contraceptive methods  
and their safety profiles.<sup>10,11</sup> Emerging evidence shows  
that the use of hormonal contraceptives may increase the  
risk for HIV transmission as well as increase the risk of  
acquisition of new HIV infection.<sup>12</sup> This evidence might  
complicate contraceptive decision-making. Accordingly,  
it is important to understand how and when adolescents  
make contraceptive decisions, what the points of access  
to these contraceptive tools are, and how appropriate  
information on contraceptive choices related to their  
SRH may be made easily accessible.

There is currently little known about factors that drive  
choice of sexual practices and sexual behaviours in ado-  
lescents in Nigeria. Evidence shows that early sex initia-  
tion increases the prospect for multiple sex partnering.  
Data from Nigeria show a large proportion of adoles-  
cents age 15 to 19 years engage in high sexual risk

<sup>8</sup> Federal Ministry of Health, Nigeria. HIV/STI Integrated Biological  
and Behavioural Surveillance Survey 2007, 2010; Federal Ministry of  
Health, Nigeria. Behavioural Surveillance Survey 2003; Federal Minis-  
try of Health, Nigeria. National HIV/AIDS Reproductive Health  
Survey 2003, 2005, 2007; National Population Commission [Nigeria].  
*op cit* note 4.

<sup>9</sup> Federal Ministry of Health, Nigeria. National HIV/AIDS Reproduc-  
tive Health Survey 2007.

<sup>10</sup> National Population Commission [Nigeria]. Nigeria Demographic  
and Health Survey 2008. Calverton, Maryland: National Population  
Commission and ORC Macro. 2009.

<sup>11</sup> H. Birungi, J.F. Mugisha, J. Nyombi, F. Obare, H. Evelia & H.  
Nyinkavu. Sexual and reproductive health needs of adolescents  
perinatally infected with HIV in Uganda. July, 2008.

<sup>12</sup> R. Heffron, D. Donnell, H. Rees, C. Celum, N. Mugo, E. Were, G.  
de Bruyn, E. Nakku-Joloba, K. Ngunjiri, J. Kiarie, R.W. Coombs & J.M.  
Baeten; for the Partners in Prevention HSV/HIV Transmission Study  
Team. Use of hormonal contraceptives and risk of HIV-1 transmission:  
a prospective cohort study. *Lancet Infect Dis* 2012; 12(1): 19–26.

behaviour. In one study, 64.7% of sexually active boys and 71.4% of sexually active girls had unprotected sex with a partner who was neither spouse nor co-habiting partner in the last 12 months.<sup>13</sup> This high risk behaviour was comparatively higher in other age groups.

Adolescents also face sexual violence and coercion in their daily lives; a growing SRH issue. The prevalence of sexual violence ranges between 15 to 40% in sub-saharan Africa<sup>14</sup> with studies showing rates of sexual coercion and abuse among adolescents in Nigeria ranging from 11 to 55%.<sup>15</sup> The report of rape ranges between 4% and 6%, with a recent study of adolescents showing 12 (0.05%) male and 69 (31.4%) female adolescents reported forced sex.<sup>16</sup>

## ADOLESCENCE AND RESEARCH

Adolescents face unique intrinsic and extrinsic challenges when considering participation in research. Intrinsic ones include developmental considerations in physiology, pharmacology, and behaviour. Extrinsic considerations are those in the community, ethical, legal, and regulatory arenas and those in the design of clinical trials for adolescents to feasibly participate.<sup>17</sup> Adolescence is divided into three broad developmental periods: early adolescence (11 to 14 years) which is cognitively dominated by concrete thought processes, with limited ability to comprehend potential consequences of risk behaviors; middle adolescence (15 to 17 years) which is characterized by the emergence of abstract cognitive processes, which revert to concrete thinking during stress; and late adolescence (18 to 19 years). Each of these periods is defined by unique cognitive and physical developmental attributes that are

<sup>13</sup> National Population Commission *op cit* note 12.

<sup>14</sup> A.O. Fatusi & R.B. Blum. Adolescent Health in an International Context: The Challenge of Sexual & Reproductive Health in Sub-Saharan Africa. *Adolescent Medicine: State of the Art Reviews* 2009; 20(3): 874–862.

<sup>15</sup> A.J. Ajuwon, A. Olaleye, B. Faromoku & O. Ladipo. Sexual behavior and experience of sexual coercion among secondary school students in three states in North Eastern Nigeria. *BMC Public Health* 2006(23); 6: 310; A.J. Ajuwon, B.O. Olley, I. Akin-Jimoh & O. Akintola. Experience of sexual coercion among adolescents in Ibadan, Nigeria. *Afr J Reproductive Health* 2001; 5(3): 120–131.

<sup>16</sup> Ibid; A.J. Ajuwon, W. McFarland, S. Hudes, S. Adedapo, T. Okikiolu & P. Lurie. Risk-related behavior, sexual coercion and implications for prevention strategies among female apprentices tailors in Ibadan, Nigeria. *AIDS & Behav* 2002; 6(3): 233–241; O.I. Fawole, A.J. Ajuwon, K.O. Osungbade & O.C. Faweya. Prevalence of violence against young female hawkers in three cities in south-western Nigeria. *Health Education* 2002; 102(5): 230–238; Federal Ministry of Health, Nigeria. Integrated Behavioural and Biological Sentinel Survey, 2007.

<sup>17</sup> B.G. Kapogiannis, E. Handelsman, M.S. Ruiz & S. Lee. Introduction: Paving the way for biomedical HIV prevention interventions in youth. *J Acquir Immune Defic Syndr* 2010; 54: S1–S4.

on a continuum.<sup>18</sup> By mid adolescence (normally around the ages of 14 to 16), the cognitive abilities of adolescents are roughly the same as biologically mature adults. Adolescents' behavioural code is frequently defined by their peer group with major conflict developing between the adolescent and parent as they strive for greater autonomy.<sup>19</sup> Late adolescence is defined by well-developed abstract cognitive processing with the peer group being replaced by more adult type close personal relationships.<sup>20</sup> It is important to understand this dynamic developmental trajectory to contextualize the variety of adherence behaviors adolescents display when it comes to their health care.

Intellectually, by mid adolescence, individuals are generally able to understand long-term risks and the benefits of research. Adolescents of the same age bracket are also frequently inclined toward risk taking, and are acutely sensitive to peer influence. These factors can affect their understanding of risks and their capacity to make consistently sound judgments about long-term benefits. This is important as research participants who consent to participate must be able to understand the long term implications of information provided about the study.

Ethical guidelines have traditionally treated adolescents as 'vulnerable,' meaning their capacity to give consent without duress may be easily compromised. This challenge requires a balance between recognizing the emerging autonomy of adolescents, their differential rates of development, and their potentially immature response to personal risk. Potential risk needs to be weighed against the potential benefits to be derived from their participation in research. Research involving adolescents needs to be designed to ensure that it takes into account these characteristics, including adolescents' tendency toward altruism,<sup>21</sup> and rebellion, influence of peer pressure, as well as their increased sensitivities around body image,<sup>22</sup> privacy, and confidentiality.<sup>23</sup>

## The Need for Distinct Data on Adolescent Populations

Adolescents represent a critically important user group for SRH products as they bear a disproportionate share

<sup>18</sup> B.J. Rudy, B.G. Kapogiannis, M.A. Lally, G.E. Gray, L.G. Bekker, P. Krogstad & I. McGowan. Youth-specific considerations in the development of preexposure prophylaxis, microbicide, and vaccine research trials. *J Acquir Immune Defic Syndr* 2010; 54 Suppl 1: S31–S42.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

<sup>21</sup> P.D. Stanford, D.A. Monte, F.M. Briggs et al. Recruitment and retention of adolescent participants in HIV research: findings from the REACH (Reaching for Excellence in Adolescent Care and Health) Project. *J Adolesc Health* 2003; 32: 192–203.

<sup>22</sup> M.S. Birkeland, O. Melkevik, I. Holsen & B. Wold. Trajectories of global self-esteem development during adolescence. *J Adolesc* 2012; 35(1): 43–54.

<sup>23</sup> P.D. Stanford et al. *op cit*. note 21.



of STIs and HIV, in addition to risks of unplanned pregnancy. The claim that it is reasonable and sufficient to extrapolate safety and effectiveness data derived from those over 18 years to younger adolescents is flawed on two levels – the physical and the social. A Global Campaign for Microbicide report notes the biologic and behavioral differences between young adolescent girls and older women justify separate safety and effectiveness data on sexual and reproductive health products.<sup>24</sup> The cervixes of younger female adolescents are not fully mature, making them biologically more susceptible to STIs. Adolescents' menstrual patterns also differ from adult women, as some 80% of adolescents will have cycles without ovulation within four years after menarche. Without ovulation, adolescents lack progesterone, which may influence the vagina's local immune responses.<sup>25</sup> At the social level, younger adolescents differ from adults in significant ways that could affect how they use SRH products.

In Nigeria, despite the stipulated legal age of consent of 18 years, a large proportion of adolescents are sexually active. The 2008 national demographic health survey (NDHS) shows that 23% of women aged 15–19 years had begun childbearing, 18% have had a child and 5% are pregnant with their first child. Also, 12.4% of male and female respondents were married by 15 years, 15.3% of women and 6.2% of men had their first sex experience by 15 years, and 29.7% of female and 6.8% of male 15–19 year old respondents had had sex within the last 4 weeks of the survey.<sup>26</sup> These data emphasize the need for early engagement of adolescents in sexual and reproductive health research that can help in the design of programmes that address their SRH needs.

Adolescent health data is important to develop evidence-based policies and programmes that support adolescent health; to increase access to and use of health services for adolescents; and to strengthen contributions from the education, media and other sectors to improve adolescent health. There are a number of reproductive health problems that are restricted to, or occur also in, adolescents which cannot be solved with existing knowledge. As a result, there is an ethical duty of beneficence and justice to conduct appropriate research to address these problems.

One of the key ways that adolescents below the age of legal consent have gained access to SRH services is

<sup>24</sup> Z. Essack, C. Slack & A. Strobe. Overcoming key obstacles to adolescent involvement in HIV vaccine and microbicide trials: A roadmap for stakeholders. Global Campaign for Microbicides: 2008.

<sup>25</sup> L.L. Heise & S.Y. Wood. Rethinking the ethical roadmap for clinical testing of microbicides. 2005. Available at: <http://www.global-campaign.org/researchethics.htm>. [Accessed 20 March 2014]; A. Strobe, C. Slack & Z. Essack. Child consent in South African law: Implications for researchers, service providers and policy-makers. *S Afr Med J* 2010; 100: 247–249.

<sup>26</sup> National Population Commission *op cit* note 10.

through assessment of competence—specifically, whether the young person can demonstrate an understanding of the nature and implications of the proposed treatment, including the risks and alternative courses of actions.<sup>27</sup> Applying a similar test in the research context would remove a major objection to enabling greater participation of minors in research – the objection that minors might not understand their range of choice and thus be more vulnerable to coercion. Applying specific and individual tests of competency, and documenting it, has a clear advantage over age-in that it recognises the developmental and cognitive differences that exist within groups of young people who mature at different rates.

## INFORMED CONSENT

Informed consent is a fundamental requirement in research participation. It is obtained through a dialogue that respects the individuality of each prospective participant and allows ample opportunity for the prospective participant to ask questions. Every research protocol must clearly explain how the study team members intend to ensure understanding and comprehension of all study information.

Informed consent must be voluntarily obtained and devoid of undue inducement and coercion. It is also described as the principle of 'respect for persons'<sup>28</sup> which acknowledges that individuals with capacity have the right to make autonomous decisions. While the capacity for autonomous decision-making varies considerably across cultures and stages of adolescence, it is important to consider that the involvement of parents (and guardians) in an informed consent process may jeopardize the autonomous decision-making of the adolescent, in addition to possibly compromising confidential information about the adolescent.

## Paediatric Regulations and Legislation

As noted in the introduction, the Nigerian Constitution<sup>29</sup> and the section 277 of the 2003 Child Rights Act<sup>30</sup> define a minor as a person under the age of 18. This implies that people under the age of 18 years have limited legal capacity and are vulnerable to decision making that is not fully competent. They therefore need a legally authorized surrogate decision maker—usually a family member to act on their behalf. Section 64(2) of the Child Rights Act

<sup>27</sup> R. Wheeler. Gillick or Fraser? A plea for consistency over competence in children. *BMJ* 2006; 332(7545): 807. doi: 10.1136/bmj.332.7545.807.

<sup>28</sup> Belmont Report, 1979.

<sup>29</sup> Federal Government of Nigeria. *op cit* note 6.

<sup>30</sup> Federal Ministry of Women Affairs. *op cit* note 7.

1 however provides that an adolescent who has attained the  
2 age of 16 years has the right to give consent for scientific  
3 investigation without parental consent. The 2011 (version  
4 7.0) National Health Research Ethics Code for Nigeria  
5 also contains provision for soliciting consent from parents  
6 or legal guardians and for obtaining assent from minors  
7 participating in research. It explicitly states in section F(c)  
8 that minors should not be excluded from research without  
9 explicit reasons for doing so.<sup>31</sup> Unfortunately, the code is  
10 not explicit about age for consent and assent. However,  
11 the working principle upheld by the National Health  
12 Research Ethics Committee is that assent needs to be given  
13 by adolescents between the ages of 12 and 17 years while  
14 their parents give consent for those who are not considered  
15 mature minors.<sup>32</sup> This is partially in line with the  
16 requirement of the Section 29(4b) of the constitution of the  
17 Federal Republic of Nigeria which states that '*any woman  
18 who is married shall be deemed of full age*'. Children below  
19 12 years in Nigeria are not however, required to give assent  
20 (personal communication, Prof Clement Adebomowo,  
21 National Health Research Ethics Committee Chair-  
22 person). The above shows clearly that for Nigeria, the age  
23 for consent for participation in research is still very  
24 unclear. It also highlights the need for the development of  
25 regulation and legislation governing adolescent engage-  
26 ment in research in Nigeria.<sup>33</sup>

## 27 Parental Consent

28 Parental consent alongside that of the adolescent is a  
29 major concern. Within the Nigerian legal context, paren-  
30 tal consent and assent for adolescents below the age of 16  
31 years is needed before participation in any form of  
32 research – except for mature minors.<sup>34</sup> This clause raises  
33 multiple ethical dilemmas. First of all, there is the legal  
34 dilemma of who provides parental consent. Singh et al.<sup>35</sup>

35 <sup>31</sup> National Health Research Ethics Committee of Nigeria, Federal  
36 Ministry of Health, Department of Health Planning and Research.  
37 National Code for Health Research Ethics version 7.0. 2007. Available  
38 at: [http://www.nhrec.net/nhrec/NCHRE\\_10.pdf](http://www.nhrec.net/nhrec/NCHRE_10.pdf) [Accessed 20 March  
39 2014].

40 <sup>32</sup> Matured minors refers to a young person who has not reached adult-  
41 hood as defined by the laws but whose maturity is such that (s)he can  
42 interact on an adult level for certain purposes such as consenting to  
43 medical care and in this case, research. Such an individual is assumed to  
44 have the capacity to understand the nature and consequences of the  
45 proposed treatment and is adjudged to have the competency to under-  
46 stand what it takes to participate in research.

47 <sup>33</sup> Federal Ministry of Health, Nigeria, *op cit* note 8.

48 <sup>34</sup> Matured minors are defined as individuals who has not reached  
49 adulthood as defined by state law but who may be treated as an adult for  
50 certain purposes. Based on the Nigeria constitution, matured minors  
51 are married adolescents.

52 <sup>35</sup> J.A. Singh, S.S. Karim, Q.A. Karim, K. Mlisana, C. Williamson, C.  
53 Gray, M. Govender & A. Gray. Enrolling adolescents in research on  
54 HIV and other sensitive issues: lessons from South Africa. *PLoS Med*  
55 2006; 3(7): e180. Epub 2006 Apr 18.

56 noted that some minors live with surrogate caregivers  
57 who are not formally appointed or legally recognised as  
58 the adolescents' guardian. In these instances, it is practi-  
59 cally impossible to seek parental consent or to determine  
60 who, if anyone, is the legal guardian to authorise an  
61 adolescent's participation in a study. In Nigeria, this legal  
62 dilemma poses challenges for the conduct of research in  
63 the field. The 2008 National Demographic Health Survey  
64 showed that 9% of those under the age of 15 years were  
65 living without their biological parents.<sup>36</sup> A recent analysis  
66 of a data collected on adolescent studies showed that  
67 18.9% of adolescents aged 10–19 years reside with guard-  
68 ians.<sup>37</sup> Research practice however limits parental consent  
69 to recognized legal guardians. The law has implications  
70 for the exclusion of adolescents participants resident with  
71 surrogate caregivers from research which could otherwise  
72 have been of benefit both to adolescent participants and  
73 the broader population. Similarly, the law does not  
74 legally identify an unmarried adolescent heading a house-  
75 hold (a situation very well recognized and documented  
76 following the HIV epidemic in many countries in Africa)  
77 as a matured minor. This action negates the principle of  
78 justice which promotes fair selection of study partici-  
79 pants, as participants' exclusion should be on the basis of  
80 their ineligibility due to scientific parameters and social  
81 protection.

82 Secondly, is the potential to compromise an adoles-  
83 cent's privacy where parental consent is sought for SRH  
84 research. For many communities in Nigeria, parents  
85 prefer to talk with their families or respected people in  
86 their community before reaching a decision about pro-  
87 viding consent for an adolescent to participate in a sexual  
88 and reproductive health research. This is especially true  
89 when research involves more invasive procedures such as  
90 blood draws and vaginal examinations. This consultation  
91 is also likely to occur if there are no clear therapeutic  
92 benefits accruable from participation in such studies, as it  
93 is the case for most HIV prevention research. It is  
94 however plausible for ethics review committees to waive a  
95 requirement for parental permission for adolescent par-  
96 ticipation when there are compelling reasons warranting  
97 this action. Such justification for a waiver must establish  
98 a case for ethical duty of beneficence and justice for the  
99 conduct of the research on this group with evidence to  
100 show the research is appropriate for the group. In  
101 Nigeria, ethics committees may have to act based on their  
102 informed discretion as the Section F(f13) of the National  
103 code provides limited guidance on this subject matter.

104 <sup>36</sup> National Population Commission *op cit* note 10.

105 <sup>37</sup> A recent national survey that evaluated the sexual and reproductive  
106 health need of adolescents living HIV in Nigeria was conducted by  
107 Positive Action for Treatment Access with funding support by Ford  
108 Foundation West Africa Office. Dissemination on study result was  
109 conducted on 14 May 2013 at Sheraton Hotel and Towers, Abuja,  
110 Nigeria.

The code states that: 'Consent in other situations, including research involving children, persons with diminished autonomy, vulnerable populations and other extraordinary situations, including waiver of consent, are described in other guidance documents issued by NHREC'.<sup>38</sup>

### Implications of Parental Consent for All Adolescent Research

Privacy and confidentiality are considered critical for adolescent enrollment in research.<sup>39</sup> Researchers struggle to strike a balance between parental involvement and the need to protect the adolescent's privacy and confidentiality especially with regards to sex and sexuality. This becomes complex when enrolling teenagers who are below the legal age for sexual consent. The principles of ethics require that researcher's respect study participant's autonomy and right to confidentiality. The assurance of data security is likely to promote adolescents' engagement in sexual and reproductive health research. Requiring adolescents to seek parental consent for their participation in the study may nullify this obligation to assure confidentiality<sup>40</sup> and may compromise the quality of generated data. In extraordinary circumstances, however, there may be a need to disclose information divulged by a minor during research to the 'legal' caregiver. For example, a 12 year old who tests HIV positive and needs to be enrolled for ARVs may need to have information disclosed to the parent in order to provide access to treatment.

Guideline 14 of the Council for the International Organisation of Medical Sciences Guidelines tries to address the potential challenges that may arise with parental consent when adolescents are enrolled in research. It states that: 'Some studies involve investigation of adolescents' beliefs and behaviour regarding sexuality or use of recreational drugs; other research addresses domestic violence or child abuse. For studies on these topics, ethical review committees may waive parental permission if, for example, parental knowledge of the subject matter may place the adolescents at some risk of questioning or even intimidation by their parents' (CIOMS, 2002).<sup>41</sup>

Zuch et al. argued that strict adherence to the implementation that require active parental consent will deter

<sup>38</sup> National Health Research Ethics Committee of Nigeria *op cit.* note 31.

<sup>39</sup> P.D. Stanford et al. *op cit* note 21.

<sup>40</sup> K. Ringheim. Ethical and human rights perspectives on providers' obligation to ensure adolescents' rights to privacy. *Stud Fam Plann* 2007; 38(4): 245–252.

<sup>41</sup> Council for International Organizations of Medical Sciences (CIOMS). ISBN 92 9036 075 5. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: CIOMS, in collaboration with WHO, 2002; guideline point 14. Available at: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm). [Accessed 20 March 2014].

from the conduct of school based adolescent sexual and reproductive health studies for a number of reasons including introduction of significant sample bias into the data.<sup>42</sup>

The complexity of obtaining parental consent hinges on balancing the requirement of the law and compliance with ethical principles because it is required that the norms and standards (both legal and ethical) that govern adolescent research in any country must be complied with. Unfortunately, there is little clarity on how to manage confidentiality in research involving adolescents. In research where parents give consent, complex privacy issues arise. As noted, a parent may give consent for enrolment, but adolescents may expect confidentiality for some components (such as their risk behaviour). There is also tension around how to manage confidentiality when the setting has laws about disclosures that must be reported to authorities. In Nigeria, the National Health Research Ethics Code provides limited guidance on this. While it recognises the need to protect research participants' privacy it does not explicitly address the implication of this with respect to adolescents engaged in research. The onus therefore currently rests with the researcher and the ethics committees to ensure that the study design ensures the privacy of any adolescent engaged in research within the ambit of existing legal frameworks while ensuring the scientific validity and the ethical integrity of the study conduct.

### PARENTAL CONSENT: REALITY IN THE FIELD

Independent of the laws and guidelines, there are cultural and social issues that may promote and support the need for parental consent prior to adolescents' engagement with research. These cultural and social issues may become the main consideration in the question on the morality of not obtaining parental permission prior to adolescent engagement in research. For example, enrolling adolescents without parental permission could alienate communities at the cost of losing support for the study.

In Nigeria, Open discussions about adolescents and issues that relate to them are limited and conservative. The perceptions and opinions of many policy makers, public opinion leaders and gatekeepers are sometime not supportive of discussion of sexual issues among adolescents. It is assumed that adolescents will be more promiscuous if they learn about sexuality and prevention of

<sup>42</sup> M. Zuch, A.J. Mason-Jones, C. Mathews & L. Henley. Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research. *BMC Int Health Hum Rights* 2012; 12: 3. doi: 10.1186/1472-698X-12-3.



1 HIV/AIDS. Furthermore, to date, scientific justification  
2 for adolescent enrolment in any research has not been  
3 articulated in a way that key stakeholders, like commu-  
4 nity representatives, can continuously appreciate.

5 Therefore, to successfully enroll and retain adolescents  
6 in research, it may be worthwhile to first of all, consult  
7 and engage the community prior to research protocol  
8 submission to the ethics committee creates the opportu-  
9 nity to discuss the rationale underpinning the inclusion of  
10 adolescents in the research, as well as the reasons for not  
11 making parental consent for an adolescent's participation  
12 in a study a requirement where such is the case. Secondly,  
13 to extensively engage adolescents, youth and parents in  
14 research design and implementation. Thirdly, to inform  
15 the adolescents about the benefits and risks of research.  
16 Fourthly, the potential challenges associated with such  
17 research design must be carefully examined and discussed  
18 in such a way that makes them understandable, and can  
19 facilitate community investment in actions to address  
20 them. The inclusion of adolescent perspectives into every  
21 stage of the research development process, especially in  
22 clinical trials is essential. Scientific experts also need to  
23 clarify the differences in adolescent and adult SRH issues  
24 thereby justifying adolescents' engagement in SRH  
25 research.

## 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54

### CONSIDERATIONS FOR INFORMED CONSENT BY ADOLESCENTS IN NIGERIA

In summary, the informed consent process should take  
into consideration the capacity of the adolescent to  
consent; the role of surrogate decision-makers who  
should be able to consent when adolescents do not have  
capacity; and possible restrictions on the autonomy of  
adolescents or their proxies to consent. Unfortunately,  
while the National Child Rights Act specifically specified  
the age limits for consenting in research, evolving evi-  
dence points to a need to lower the current age for con-  
senting to enable younger adolescents engage in research  
that can inform programme development and program-  
ming apt to address their needs.

One major concern about adolescents is their ability to  
comprehend. As medical evidence shows, cognitive devel-  
opment of the adolescents is near that of the adult by 14  
years such that '*decision making and reasoning ability is as  
good as that seen in adulthood and involves the flaws*'.<sup>43</sup> It  
may therefore be important to advocate for changes in

<sup>43</sup> A.C. Peterson & N. Leffert. Developmental issues influencing guide-  
lines for adolescent health. *Journal of Adolescent Health* 1995; 17: 298-  
305; C. Lewis. How adolescents approach decisions: changes over  
grades seven to twelve and policy implications. *Child Development* 1991;  
52: 538-544.

the law so it can permit adolescents 14 years and above  
with proven evidence of sufficient maturity, and with the  
mental capacity to understand the benefits, risks, and  
social and other implications of the outcome, to partici-  
pate in research in general and sexual and reproductive  
health research specifically, without parental consent. It  
is now for the ethics committees to be able, each within its  
peculiar cultural context, to calculate the risk and-benefit  
for the research and adjudge that the implementation of  
such research would not expose the adolescent to undue  
risk taking cognisance of age and cultural peculiarities. In  
addition, sexual and reproductive health research proto-  
cols that would engage adolescents who are 14 years old  
should critically appraise the informed consenting pro-  
cessing and evaluate for perceived threats to consent such  
as inadequate education and developmental characteris-  
tics of adolescents engaging in decision-making. It may  
be inappropriate to assume that all 14 year olds in  
Nigeria should be excluded from parental consent prior  
to engagement in sexual and reproductive health  
research. Rather, researchers may need to always develop  
tools and processes to impart information, assess under-  
standing, and enhance the voluntariness of decisions to  
participate in SRH research conducted in adolescents  
particularly those that require therapeutic interventions.  
Researchers should ensure the adolescent demonstrates  
capacity for comprehension and required actions.

When ethics committees do not feel confident that the  
risk associated with research are acceptably low, parental  
consent for research participation may be required. Thus,  
consent norms for adolescent research participation  
needs to reflect the reality that research is of varying  
complexity and risk. For simple and low-risk research,  
exceptions to the norm of parental consent may be appro-  
priate, provided that other protections are in place,  
including competent ethical reviews. In addition, commu-  
nity endorsement of research plans should be a major  
factor in research ethics committee consideration on  
whether to allow adolescents to provide autonomous  
consent for participation in a study. The World Health  
Organisation provides comprehensive guidelines on  
engagement of adolescent in research which could serve  
as a useful guide for research protocol review.<sup>44</sup>

While the ethical-legal framework for consent is speci-  
fied in Nigeria, its understanding and application by  
ethics reviewers needs to be addressed through trainings.  
This is underpinned by the work of the New HIV Vaccine  
and Microbicide Advocacy Society (NHVMAS) which  
has been engaged for over 5 years in building the capacity  
of ethics reviewers in the country on the ethics of bio-  
medical HIV prevention research. These trainings are

<sup>44</sup> World Health Organisation. Position paper of the scientific and  
ethical review group on reproductive health involving adolescents.  
Available at: [http://www.who.int/reproductivehealth/topics/ethics/  
adolescents\\_guide\\_ser/en/index.html](http://www.who.int/reproductivehealth/topics/ethics/adolescents_guide_ser/en/index.html). [Accessed 20 March 2014].

1 conducted in such a way that ensures knowledge and  
2 skills acquired are applicable to other research fields.<sup>45</sup>

3 The most notable study about ethical involvement of  
4 adolescents in research is the HPV vaccine study which  
5 resulted in the licensing of HPV to prevent cervical and  
6 anal cancers in adolescents. This is one successful story in  
7 the conduct of ethical trials that engages adolescents on  
8 health issues of particular concern to them.<sup>46</sup>

9 Within the African continent, there are recognizable  
10 efforts in South Africa focused at addressing adolescent  
11 engagement in sexual and reproductive health research.  
12 The engagement of 16 year old adolescents in the  
13 Carraguard study is a step in this direction.<sup>47</sup> The pro-  
14 posed engagement of adolescents in post CAPRISA 004  
15 studies is also one effort in this direction.<sup>48</sup> More recently,  
16 the engagement of 12–17 year old in the SASHA project  
17 which was preparing adolescents for HIV Vaccine  
18 research in South Africa.<sup>49</sup>

19 Locally, adolescents have long been engaged in multi-  
20 ple social science and epidemiological researches. The  
21 Integrated Behavioural and Biological Sentinel Surveys,  
22 the National HIV/AIDS Reproductive Health Surveys  
23 and the NDHS engaged participants aged 15 years.<sup>50</sup> The  
24 studies capture issues relevant to sexual and reproductive  
25 health.

26 The authors feel that in view of the cultural sensitivity to  
27 open discussion about sex, the ethics of engagement of  
28 adolescents in sexual and reproductive health research  
29 may be an issue of debate for a while to come. A starting  
30 point may be the conduct of a workshop to resolve various  
31 dilemmas about the ethics of engaging adolescents in  
32 sexual and reproductive health studies, some of which  
33 have been highlighted in this paper. This workshop may  
34 provide the ground for starting to think through the ethics  
35 of engagement of youths in SRH research in the Nigerian  
36 environment more specifically taking cognizance of  
37 Nigeria's peculiar, diverse and sometimes contradictory  
38 traditional, religious, legal and social systems.

40 <sup>45</sup> M.O. Folayan, A. Adaranijo, F. Durueke, A.J. Ajuwon, A.A.  
41 Adejumo, O. Ezechi, K. Oyedeji & O. Akanni. Impact of three years  
42 training on capacity of ethics committees in Nigeria. *Developing World*  
43 *Bioethics* 2012; Sep 24. doi: 10.1111/j.1471-8847.2012.00340.x.

44 <sup>46</sup> J. Paavonen, P. Naud & J. Salmerón et al. Efficacy of human  
45 papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical  
46 infection and precancer caused by oncogenic HPV types (PATRICIA):  
47 final analysis of a double-blind, randomised study in young women.  
48 *Lancet* 2009; 374(9686): 301–314.

49 <sup>47</sup> ClinicalTrials.gov. Efficacy study of the vaginal gel Carraguard to  
50 prevent HIV transmission. Available at: [http://clinicaltrials.gov/show/  
51 NCT00213083](http://clinicaltrials.gov/show/NCT00213083). [Accessed 20 March 2014].

52 <sup>48</sup> FACTS 002 is a planned Phase II safety study to test tenofovir gel use  
53 in sexually-active young women 16 and 17 years of age. Available at:  
54 <http://www.facts-consortium.co.za/> [Accessed 20 March 2014].

55 <sup>49</sup> Press release: SASHA project preparing for adolescent HIV vaccine  
56 trials in South Africa completed. Available at: [http://www.edctp.org/  
57 Press\\_release.401+M5a547e2d46d.0.html](http://www.edctp.org/Press_release.401+M5a547e2d46d.0.html). [Accessed 20 March 2014].

58 <sup>50</sup> Federal Ministry of Health, Nigeria, *op cit* note 8.

## CONCLUSION

The ethical dilemma of engaging adolescents in SRH research is intertwined with legal and regulatory issues. For example, the appropriateness of including adolescents in research when the risks are more than 'low' or 'minor increase over minimal' is a difficult and thorny ethical issue. Consideration should be given to adolescents to consent unassisted to participate in research as long as the parents or legal guardians or the community is unlikely to object to the adolescent's participation and the study protocol justifies why adolescents should be included as participants.<sup>51</sup>

Ethical guidelines in Nigeria should consider the feasibility of engaging adolescents aged 14 years and above (rather than the current consideration of 16 years and above) in research without the need for parental consent. The peculiar challenges of applying fundamental ethical principles for adolescents engaged in research especially in cultures sensitive to open and public discussions about sex and sexuality, and how to resolve them can only be learnt from practical field experiences. Ethics is an ever evolving field and ethical consideration of adolescents' engagement in sexual and reproductive health research shall continue to constitute central themes in many ethical discourses for a while to come.

### Biographies

**Morenike Oluwatoyin Folayan** is an Associate Professor in the Department of Child Dental Health, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria.

**Bridget Haire** is a lecturer at the Centre for Values, Ethics and the Law in Medicine, University of Sydney and Vice President of the Australian Federation of AIDS Organisations.

**Abigail Harrison** is Assistant Professor (Research) in the Department of Behavioral and Social Sciences, School of Public Health, Brown University, in Providence, Rhode Island, and an affiliate of the International Health Institute and Population Studies and Training Center. Her research addresses adolescents, gender, HIV/AIDS and reproductive health in sub-Saharan Africa.

**Morolake Odetoingbo** is the Executive Director of Positive Action for Treatment Access; a non-governmental organization focused on addressing the needs of people living with HIV in Lagos, Nigeria.

**Olawunmi Fatusi** is an Oral and Maxillofacial Surgeon. She is the current Dean of the Faculty of Dentistry, College of Health Sciences, Obafemi Awolowo University, Ile-Ife, Nigeria.

**Brandon Brown** is the Director of the Global Health Research, Education and Translation program at the University of California – Irvine.

<sup>51</sup> Ethics in Health Research: Principles, Structures and Processes. Pre-  
toria: Department of Health; 2004.



## AUTHOR QUERY FORM

Dear Author,

During the preparation of your manuscript for publication, the questions listed below have arisen. Please attend to these matters and return this form with your proof.

Many thanks for your assistance.

Query References	Query	Remarks
1	*AUTHOR: The page range '874-862' seems to be incorrect; please check.	

*Note:* The query which is preceded by \* is added by Toppan Best-set.