



Government of Kenya  
Ministry of Health

# Guidelines for Conducting Adolescent HIV Sexual and Reproductive Health Research in Kenya





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National AIDS and STI Control Programme (NASCOP)  
Ministry of Health Government of Kenya



Kenya Medical Research  
Institute (KEMRI)



International AIDS Vaccine  
Initiative (IAVI)



LVCT Health

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# CONTENTS

ABBREVIATION AND ACRONYMS.....	VII
ACKNOWLEDGEMENTS.....	VIII
OPERATIONAL DEFINITIONS.....	IX
FOREWORD.....	XI
AT A GLANCE.....	XII
A BRIEF SUMMARY OF THE GUIDELINES HIGHLIGHTING 10 KEY COMPONENTS.....	XII
RATIONALE FOR PARTICIPATION OF ADOLESCENTS IN SRH RESEARCH.....	XII
<b>1 INTRODUCTION.....</b>	<b>1</b>
1.1 Context.....	1
1.2 Defining adolescents: Kenya’s Dilemma.....	7
1.3 Rationale for Participation of Adolescents in Research.....	8
1.4 Guiding Ethical Principles.....	9
1.5 Role of Institutional Review Boards in Research Involving Adolescents... ..	10
<b>2 ETHICAL CONSIDERATIONS.....</b>	<b>11</b>
2.1 Developing Research Protocols on Research with Adolescents.....	11
2.2 Consent, Assent, and Parental/Guardian Permission.....	11
2.3 Privacy and Confidentiality.....	16
2.4 Evaluation of Risks and Benefits.....	19
2.5 Payment for Adolescents Participation in Research.....	21
2.6 Research with Adolescents Using Social and New Media.....	23
<b>3 INVOLVING SPECIFIC ADOLESCENT POPULATIONS IN RESEARCH.....</b>	<b>24</b>
3.1 Vulnerable Adolescents.....	24
3.2 Adolescents in School.....	25
3.3 Adolescent Belonging to Specific Populations.....	25

4	<b>STAKEHOLDERS ENGAGEMENT</b> .....	27
4.1	<b>Creating Ownership and Support when Involving Adolescents in Research</b>	27
5	<b>RECOMMENDED RESOURCES</b> .....	29
	<b>LIST OF CONTRIBUTORS</b> .....	30

# ABBREVIATION AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome	KEMRI	Kenya Medical Research Institute
DCS	Department of Children's Services	LGBT	Lesbian, Gay, Bisexual and Trans-gender
CDC	Center for Disease Control	LVCT	Liverpool Voluntary Counselling and Testing
CFR	Code of Federal Regulations	MoEST	Ministry of Education, Science and Technology
CHR	Committee on Human Research	MoH	Ministry of Health
CIOMS	Council for International Organization of Medical Sciences	MSM	Men who have Sex with Men
ERC	Ethical Review Committee	NASCOP	National AIDS and STI Control Programme
FHOK	Family Health Options Kenya	NOPE	National Organization of Peer Educators
HIV	Human Immunodeficiency Virus	PrEP	Pre-exposure Prophylaxes
IAVI	International AIDS Vaccine Initiative	TasP	Treatment as Prevention
ICL	I Choose Life	SRH	Sexual and Reproductive Health
IRB	Institutional Review Board	UNICEF	United Nations Children's Fund
KDHS	Kenya Demographic and Health Survey	UON	University of Nairobi
KAIS	Kenya AIDS Indicator Survey	UOM	University of Manitoba
KAVI	Kenya AIDS Vaccine Initiative	WHO	World Health Organization
KASF	Kenya AIDS Strategic Framework		
KELIN	Kenya Legal and Ethical Issues Network		

# ACKNOWLEDGEMENTS

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The initiative to develop this document was conceived at a national stakeholders forum on best practices in conducting HIV research with adolescents in June 2014, under the leadership of NASCO P, IAVI, LVCT Health and KEMRI. NASCO P would like to acknowledge the support and contributions from Nembu Girls High School, UNICEF, UON-KAVI, KELIN, ICL, FHOK, NOPE, Global Communities, CDC and the Ministry of Education, Science and Technology (MoEST).

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**Dr Martin Sirengo**  
Head NASCO P



**Prof Solomon Mpoke**  
Director KEMRI



# OPERATIONAL DEFINITIONS

This section explains technical words and related terms used within this document.

Adolescent	Individual in the state of development between the onset of puberty and maturity; definitions vary according to culture and custom (Kenya has adopted the WHO definition: 10 – 19 years)
Age of consent	Age at which an individual may give consent to sexual activity with another person
Assent	Affirmative agreement of a child
Benefit	A valued or desired outcome; an advantage
Child/minor	Person who has not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted
Community advisory board	A group of volunteers that serve as a link between a community and researchers and may review and monitor research studies and help teach the community about the studies.
Confidentiality	Conditions under which information revealed by an individual participant in a relationship of trust will not be disclosed to others without permission
Consent	Affirmative agreement of an individual who has reached the legal age
Dissent	Disagreement; withholding of consent
Ethics	Fundamental principles that define values and determine moral duties and obligations
Emancipated minors	Status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities, such as self-support, marriage or procreation
Institutional review board	An independent panel of individuals, who review research proposals to ensure that the ethical principles are incorporated into the study design, that the proposed research activities include no unnecessary risks, that potential risks to study participants are minimized, and that overall potential benefit to the individual, or to society, is reasonable in relation to the risks. Also referred to as Ethical Review Committee (ERC)
Guardian (as defined by law)	An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care/Individual authorized to give consent for participation on behalf of a child
Guardian (as defined by the community)	An individual, though appointed by law, is recognized by community as the authorised caregiver to the child and is therefore authorised to give consent for participation on behalf of the child.
Informed consent	The permission given by an individual who understands the purpose and nature of a study, what participation in the study requires of the individual, the nature of the risks and what benefits are intended to results from participation in the study
Mature minors	Minors 15 years of age or older; living separate and apart from their parents or guardian, whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence, and managing their own financial affairs, regardless of the source of income

Minimal Risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
Orphan	A child without a living parent
Participant	Individual who provides data in the information-gathering activity; participants may include children and parents or guardians
Permission	Agreement of parent(s) or guardian(s) to their child's participation in research
Protocol	Document that describes objective, methodology, study design, and management of an information-gathering activity in programs and research
Research	Performing a methodical study in order to prove a hypothesis or answer a specific question. Research must be systematic and follow a series of steps and a rigid standard protocol.
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.
Vulnerable child	Child whose survival, wellbeing, or development is threatened by their social, environmental or health conditions

# FOREWORD

Despite the consensus on need to ensure equitable participation of adolescents in research, no guidelines specific to involvement of adolescent in research exist in Kenya, making it increasingly difficult to conduct research within this population. For instance, there are no clear guidelines on norms and standards (both legal and ethical) that govern adolescent HIV and sexual and reproductive health (SRH) research.

This guideline is thus the first initiative in response to a need for practical guidance on conducting research with adolescents in Kenya. It addresses a range of ethical and legal dilemmas based on expert discussions and consensus, and international guidelines and literature review on lessons learnt in other countries. It also provides a framework to interpret the ethical and legal regulations for protection of adolescent participants in research, in light of the unique legal, ethical and contextual issues that affect adolescents in Kenya. The document is about adolescents (10 - 19 years) and does not target children below 10 years. It is for use by researchers and institutions dealing with adolescents' HIV and SRH issues. In particular, the guidance document:

- highlights the emerging issues and the ethical-legal framework for conducting research with adolescent populations in Kenya;
- highlights the different approaches to ethical norms for conducting research with adolescents in similar contexts in Africa and other regions;
- provides guidance to researchers when designing research involving adolescents;
- serves as a resource for IRBs and other institutions involved in reviewing research projects that involve adolescents; and
- harmonises and contribute to the current ethical norms on research involving adolescents in Kenya.

Development of the document was informed by the cognition that exclusion of adolescents from research can lead to inadequate understanding of their particular needs and consequently, failure to deliver interventions that reflect and target the needs of this special group. The process began with a national stakeholder's consultative forum on key considerations and best practices in conducting HIV research with adolescents in Kenya, which took place in June 2014. The forum had four key objectives: (i) to share lessons and document best practices for conducting HIV research among adolescents, (ii) to build consensus on how to ensure equitable participation of adolescents in biomedical, behavioral and structural research to inform development of a guidance document, (iii) to provide leadership towards ensuring ethical and safe participation of adolescents in HIV interventions, and (iv) to initiate dialogue among stakeholders towards development of guidance for conducting research among adolescents.

It is my expectation that this long awaited guidance document will provide the necessary framework for quality and ethical implementation of behavioral, operational and biomedical research with adolescents in Kenya. On behalf of the government of Kenya, I would like to thank all stakeholders involved in the extensive participatory process that led to the development of this comprehensive guidance document. We now hold a moral duty and an urgent obligation to deliver better approaches and health technologies suitable for the next generation. I urge all research stakeholders to ensure compliance to ethical principles outlined in this guidance document in order to ensure that adolescents are not left behind but reap all the benefits of a healthy generation outlined in the Kenya Vision 2030.



**Dr. Nicholas Muraguri**  
Director of Medical Services

# AT A GLANCE

A brief summary of the guidelines highlighting 10 key components

## 1 Rationale for participation of adolescents in SRH research

- Participation of adolescents in research is generally accepted in international guidelines and documented in literature.
- Research involving adolescents is important to obtain accurate data and develop optimal interventions for this population. At the same time, adolescents are inherently more vulnerable to coercion than adults and require a higher level of protection.
- Research with adolescents should abide by principles of respect, beneficence and justice, and protect adolescents without denying them opportunity for evidence based interventions.

## 2 Development of research protocols on research with adolescents

The investigator should address the following:

- Provide scientific justification for including adolescents in the research, including the unique outcomes, benefits, and risks that will be derived from studying adolescents and that the information to be gained could not scientifically be obtained from adult subjects.
- Ensure a clear strategy for addressing social harm and managing socio-political risks.
- Adolescents and younger children should ideally not be exposed to risk where older subjects are scientifically suitable. When the research question is specific to adolescent health, then research involving this age group is ethically justifiable.
- Include adolescents in community advisory boards to ensure the voice of the adolescent is resonant through the research process, that is, from protocol development, community entry and project implementation.

## 3 Developing adolescent friendly informed consent process

- Informed consent in research is a process, and as required for all study participants, adolescents enrolling in research must be capable of understanding the purpose, procedures, risks, benefits, and alternatives of the research, and consent must be voluntary.
- Researchers should seek assent of the adolescent according to his/her level of development and capacities. However, when the adolescent develops the legal capacity to provide a fully informed consent (in the case of emancipated or mature minors) or attains the legal age of majority during the research, researchers should seek an informed consent.
  - This takes away the requirement for parental/guardian consent
  - The dissent of the adolescent, who is capable of understanding, **MUST** be respected. Where the parents or the legal guardian gives permission, but the adolescent refuses to participate in the research, that refusal must be respected and the adolescent cannot be enrolled to participate in research
  - Waiver for parent consent can be sought from IRB in presence of special conditions
    - Orphaned older adolescent who heads a household
    - Living in an institution (IRB would guide on who should provide consent)
    - Pregnant adolescent
    - Adolescent who is already a parent
- Decision for requiring one or both parents to give permission for the adolescent to participate should be based on levels of risks involved in the research.
- In certain cases, research may be conducted for conditions or for a population for which parental/guardian permission for inclusion in research is not a reasonable requirement to protect the participants.

## 4 Evaluation of risks and benefits for adolescent participation in research

Benefit should outweigh harm at all times

- If the adolescent will not benefit directly from the research, he or she should not be exposed to more than minimal risk.
- The participation of an adolescent in research should offer the possibility of a direct benefit to his/her health.
- Where no direct benefit is likely, the results should benefit other adolescents of the same age or with the same disease, exposure, condition or disability, and the adolescent should not be exposed to more than minimal risk.
- Consideration of potential harms should include harms that are physical, psychological, social or financial, as well as harms that may affect individuals or communities.
- Cumulative harms should be considered in assessing the individual harms that occur from research participation.
- Potential harms should be evaluated from the perspective of the adolescent.
- In justifying risk, participation of an adolescent in research should offer hope of direct benefit for them.
- When the research holds out the prospect of direct benefits, risks should be measured against these anticipated benefits.
- Younger participants should not be enrolled when older adolescents or adult are scientifically suitable engagement as research participant.

## 5 Ensuring confidentiality of adolescent participation in research

The ethical principle of confidentiality must be adhered to in research involving adolescents.

- Even when permission to the participation of adolescents is granted by parents or by both adolescents and their parents, confidentiality must be maintained.
- A parent/ guardian may give permission for enrollment, but adolescents' confidentiality for some components (such as their risk behaviour, sexual orientation and practices, family planning options) must be maintained.
- In order to ensure that privacy and confidentiality are maintained, researchers should adopt appropriate and reasonable safeguards, subject to applicable legal-ethical frameworks.
- In circumstances where researchers believe they are obligated to report adolescent behaviour to any authorities, the adolescent subject must be made aware of the possibility of such reporting prior to their involvement in the research.

## **6 Payment for participation in research for both parents/guardians and adolescents**

- Researchers should stipulate and disclose all types of compensations and incentives to both parents/guardians and adolescents for their participation in research (e.g. transportation reimbursement, meals, accommodation, clothes, etc.)
- Compensations must be fully disclosed during the informed consent process with both parents and adolescents
- Parents should never be paid for the participation of their adolescents in research, other than reimbursement of their expenses and compensation for their time.
- The adolescent should still be entitled to receive the appreciation compensation for his/her participation:
- Researchers may withhold part or all of the compensation if participants are excluded from the research for noncompliance. However, the adolescents should not be denied compensation to which they are entitled, due to the non-compliance of the parents.
- When determining the appropriate compensation, researchers should
  - Consider what is being paid for (e.g. time, lost earnings, inconvenience, discomfort, expenses related to the research, etc.) and
  - who will receive the compensation that is, the adolescents, the parent/ guardian or both; and risks related to participation in the study.

## **7 Research with specific population adolescents**

- While researchers working with key populations in general must abide by ethical guidelines to protect their participants as any other human subjects require protection, additional steps may be required for safe and effective engagement adolescent key populations given the challenging legal and social contexts.
- The unintended consequences of research intending to generate knowledge and evidence on key populations can include heightened stigma and increases in human rights violations, including violence.
- Careful consideration of the potential negative consequences of “minimal risk” is of special importance in research with adolescent key populations in regard to study conception, design, implementation, and dissemination.

## **8 Research with adolescent using social and new media**

- Researchers are advised to take steps to authenticate participants. For example, investigators can provide each study participant (in person) with a Personal Identification Number (PIN) to be used for authentication in subsequent computer and internet based data collection.
- Parental consent may be needed when information is potentially identifiable. Identifiable information makes risks to individuals higher and may mean that the safety net of parental consent is preferable.
- There is also a need to consider whether seeking parental consent would make things worse e.g., by putting an adolescent from a dysfunctional home at risk or result in disclosure to the researcher of additional identifying information about the identity and location of the young person. Parental consent may be “contrary to the best interests” of the adolescent when it offers no protection or makes matters worse.

## 9 Stakeholders to engage and creating good political and policy environment when conducting research with adolescents.

- Generally, engagement (and, ideally, active participation and support) of adolescent stakeholders and gatekeepers in the community is recommended before research can be undertaken: adolescents, teachers, religious/spiritual leaders, community elders, local government representatives and health, education and social services ministries, media, and organizations working on adolescent issues.
- Ensure a comprehensive and culturally sensitive dissemination plan with all stakeholders – including adolescent friendly dissemination tools (in both traditional and new media)
- Provide clarity of study findings and their implications for policy and practice changes – including the benefits to adolescents
- Prepare for crisis-management of potential back-lashes with socio-political sectors of the society should findings generate or infringe on existing cultural, religious or political norms.
- Ensure clarity in post-trial access plans should your research prove successful and acceptable by the community and government.

## 10 IRB review process for research involving adolescents

- The Institutional Review Board (IRB) reviewing research protocols involving children and adolescents should be multidisciplinary and independent.
- IRB membership should include those with experience in adolescent issues. Where none of the members has such expertise, the IRB should seek the advice of an *ad hoc* expert.
- The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective participants.

*“One thing that you should not do when conducting research with adolescents is, do not look too serious.*”

*Seek to be my friend first, because I cannot talk to a stranger. Otherwise, we cannot trust you to tell you our stories.*

*Use the language we understand and you have to see things from our perspective. Only then, I will see it from your perspective.*

*Respect my decisions and sometimes, it might change.*

*After collecting information, kindly give me feedback.*

*Come to us from the beginning and not at the end only.”*

### **Adolescent Voices**

*During National Stakeholders Forum on Considerations for Conducting HIV Research with Adolescents in Kenya*



# INTRODUCTION

*“The best interests of the child shall be a primary consideration in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies”*

Laws of Kenya: The Children Act, Chapter 141

## 1.1: Context

It is estimated that 43 percent of Kenya’s total population is below the age of 15 years. Additionally, the segment of the population aged 10 to 19 years, also referred to as adolescents constitute about a quarter of Kenya’s total population<sup>1</sup>. As families, communities and the country struggle to prepare these young people by equipping them with knowledge and skills to exploit their full potentials, the adolescents encounter such difficult and challenging situations, that if not tackled comprehensively places them at high risk of undesired outcomes such as: early child bearing; unintended

pregnancies; unsafe abortions; sexual exploitations; sexually transmitted diseases including HIV and AIDS; involvement in drugs and substance abuse; and, high levels of poverty<sup>2</sup>. Although the government of Kenya has made attempts in creating an enabling policy environment for adolescent and youth sexual and reproductive health (SRH)<sup>3</sup>, challenges in this area still exist.

The following is an overview of the 2014 adolescent and youth HIV fact sheet<sup>4</sup>, derived using data from KAIS 2012 and MOH 2012 Kenya HIV estimates.

1 2009 Kenya Census

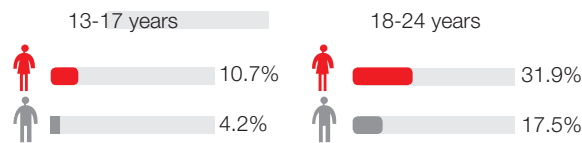
2 Republic of Kenya (2008) First Medium Term Plan (2008 - 2012)

3 National Adolescent Reproductive Health and Development Policy (2003), National Youth Policy (2007), Education Sector Policy on HIV and AIDS (2014), National School Health Policy (2009), and National Guidelines for provision of Youth Friendly Services (2005)

4 NASCOP, LVCT Health and UNICEF: Adolescent, Youth and HIV in Kenya. 2014 fact Sheet

## Sexual Violence and HIV and AIDs among adolescents and youth in Kenya

### Sexual Violence Prior to Age 18 by Sex and Age group

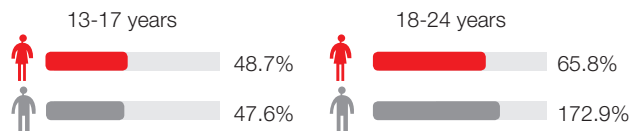


Females more likely to experience SV before age 18

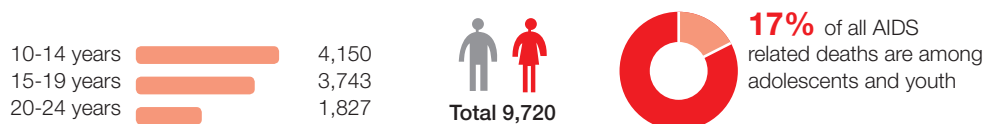
### Sexual and gender based violence

Sexual and Gender-Based Violation (SGBV) is highest among A&YW. SGBV increases biological vulnerability to HIV, reduces ability to negotiate for safer sex, with long-term psychosocial outcomes that impact sexual risk taking behaviour. According to studies on violence against children (VAC Report), 30% females experience sexual violence during childhood.

### Physical violence prior to age 18 by sex and age group



### AIDs related deaths by age



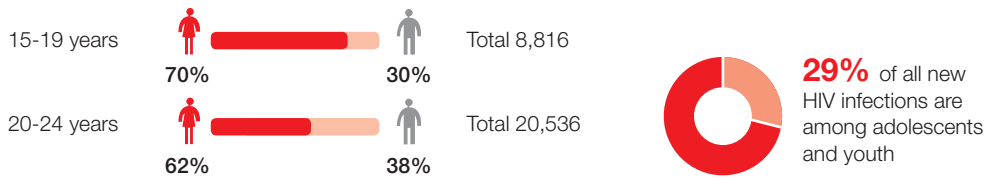
### National HIV prevalence



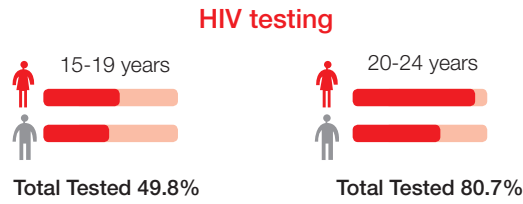
### Adolescents and youth living with HIV



### New HIV infections

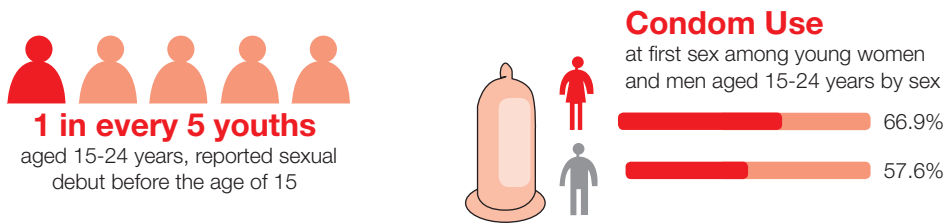


The numbers of new infections among 15 – 24 years old is very high. It is important to note that at age 10 the ratio of new infections between boys and girls is 1:1 but increases to 1:4 respectively by age 24, showing the high vulnerability of girls. 21% of new adult HIV infections occurred among young women 15-24 years. Approximately 29% of all new HIV infections are among adolescents and youth. And of all people living with HIV in the country, 16% are adolescents and youth. This explains why HIV is the leading cause of death amongst adolescents in the country.



It is encouraging to note that young people are getting to know their HIV status, albeit the fact that more females know their status, national data on awareness is at 53%. The higher knowledge of status among women can be attributed to PMTCT programmes which expectant mothers the access to HIV testing services.

### Sexual debut and condom use among adolescents and youth in Kenya



Early sexual debut amongst 15 – 24 year olds increases risk of sexually transmitted infections. Early Pregnancy is an indicator of unprotected sex and no contraception use, which subsequently increases a young woman’s economic and emotional dependency and is associated with school dropout and decreased access to economic opportunities and resources

ISSUE	DATA DIMENSIONS
Age of sexual debut among adolescents and youth	<ul style="list-style-type: none"> <li>• 85% aged 15 – 24 yrs are sexually active</li> <li>• 66.1% of females aged 15-24 years have had sex</li> <li>• By age 18 years, 59% of girls aged 15-19 have had sex</li> <li>• 12% of girls aged 15-19 years had first sex before age 15</li> <li>• By 15 years, 11.6% of adolescent girls have had sex at least once</li> <li>• Average sexual debut for women is 17 years of age (men -16 years)</li> <li>• About 70% of all pregnancies occur among women below 24 years</li> <li>• 1 out of 4 Kenyan teenage adolescent girls aged between 15 – 16 years have already begun child bearing</li> <li>• 1 in every 5 youth aged 15-24 years reported sexual debut before the age of 15</li> </ul>
Condom use	<ul style="list-style-type: none"> <li>• Only 11% of women aged 15 – 24 yrs (43% for male counterparts) used the condom consistently with partners of discordant or unknown HIV sero-status in the past 12 months</li> <li>• Promotion of female condom is low and the commodities are largely inaccessible to many</li> </ul>
HIV prevalence among adolescents and youth in Kenya	<ul style="list-style-type: none"> <li>• The overall HIV prevalence among youth aged 15-24 years is 3.8%.</li> <li>• Of the approximately 88,000 adult HIV infections annually, 21% occur among girls and young women aged 15 – 24 years.</li> </ul>
New HIV infections among adolescent and youth in Kenya	<ul style="list-style-type: none"> <li>• 21% of new adult HIV infections occurred among young women 15-24 years.</li> <li>• 29% of all new HIV infections are among adolescents and youth.</li> <li>• 16% of all people living with HIV in Kenya are among adolescents and youth explains why HIV is the leading cause of death amongst adolescents in the country.</li> </ul>
AIDs related deaths among adolescents and Youth in Kenya	<ul style="list-style-type: none"> <li>• 17% of all AIDS related deaths in Kenya are adolescents and youth</li> </ul>
ART coverage	<ul style="list-style-type: none"> <li>• 58% of adolescents living with HIV access ART</li> <li>• 42% adolescents living with HIV do not access life saving treatment</li> <li>• 16% of all people in need of ART are adolescents and youth</li> </ul>
Knowledge of HIV status	<ul style="list-style-type: none"> <li>• Approximately 50% of adolescents 15 – 19 years know their HIV status; 50% do not</li> <li>• Approximately 81% of youth aged 20 – 24 years know their HIV status; about a fifth do not</li> <li>• HIV prevalence increases with age: 1.1% amongst 15-19 year olds (0.5% in rural areas and 2.2% in urban areas); 4.6% amongst young women aged 20-24 years (over three times more likely to be infected than young men of the same age group (1.3%); 7.9% among women 25-29 years</li> <li>• 57% of women aged 15 – 24yrs (38% for male counterparts) are aware of the HIV status of sex partner in the past 12 months.</li> </ul>

ISSUE	DATA DIMENSIONS
Knowledge of SRH and HIV prevention	<ul style="list-style-type: none"> <li>70% of pregnancies in Kenya are among women below age 24</li> <li>44% of adolescents age 15-19 have never heard of Family Planning methods</li> <li>29.7% of married women aged 15-19 and 30.1% of those aged 20-24 have an unmet need for FP</li> </ul>
Access to SRH services	<ul style="list-style-type: none"> <li>Limited access to information on prevention, care and treatment by A&amp;YW</li> <li>High unmet FP need among sexually active A&amp;YW.</li> <li>This results in unwanted pregnancies, school drop-out, early marriages, abortions, and greater dependency on sex partners</li> </ul>
Orphans and vulnerable	<ul style="list-style-type: none"> <li>Kenya has a huge OVC population estimated at 2.6million</li> <li>Estimated number of OVC &lt; 18 years of age : 2.6m (Females: 1.27m)</li> <li>777,000 are female OVC aged 10 - 17 years.</li> </ul>
Sexual violence and sexual exploitation	<p>The Violence against Children report shows that:</p> <ul style="list-style-type: none"> <li>30% females experience SV during childhood;</li> <li>24% of females 18-24 years reported unwanted first sexual intercourse prior to age 18.</li> <li>Intimate Partner violence is also rife in this cohort with 47.3% of females aged 18-24 reporting first sexual violence incident prior to age 18 being perpetrated by a boyfriend/girlfriend/partner.</li> <li>About 33% adolescent girls raped by the time of 18 years in Kenya;</li> <li>22% of adolescent girls aged 15-19 report their first sexual intercourse to have been forced and few receive treatment.</li> </ul>
School enrolment and retention	<ul style="list-style-type: none"> <li>A total of 74.5% of all primary school children transition to Secondary School. Of this transition rate for girls is 71.6% girls</li> <li>Whereas 49.4% of all primary school enrolments are girls, at university enrolment this percentage had reduced to 40.5% [ 2013/14 statistics]</li> <li>20% of adolescent girls never attend school at all while only 57% complete primary education. This is attributed to a range of socio cultural and economic factors.</li> </ul>

Despite policies, legal frameworks and guidelines addressing adolescent and youth reproductive health issues existing in Kenya, researchers and programmers still face significant challenges in addressing adolescent SRH issues. Complexities of gender-based violence, stigma (of adolescents living with HIV, adolescent key populations, adolescent with disabilities), perceived lack of autonomy to make informed consent, vulnerability to inducements, cultural norms on sexuality constitute some of the ethical challenges in providing HIV and SRH services and conducting research with adolescents. This, in addition to low research literacy among adolescents has led to neglect of a very important segment of the population in research, especially HIV research.

## 1.2: Defining adolescents: Kenya's dilemma

Adolescents are individuals who are between childhood and adulthood, in the process of reaching sexual maturity. The adolescence period is combination of physical, psychological and social changes and may be divided into extensive and continuum developmental periods defined by unique cognitive and physical developmental attributes. The adolescent period may be further categorized as early adolescence (10–14 years) and late adolescence (15–19 years). Early adolescence is at this stage that physical changes

generally commence, usually beginning with a growth spurt and soon followed by the development of the sex organs and secondary sexual characteristics. These external changes are often very obvious and can be a source of anxiety as well as excitement or pride for the individual whose body is undergoing the transformation. Late adolescence encompasses the latter part of the teenage years. The major physical changes have usually occurred by now, although the body is still developing. The brain continues to develop and reorganize itself, and the capacity for analytical and reflective thought is greatly enhanced. Peer-group opinions still tend to be important at the outset, but their hold diminishes as adolescents gain more clarity and confidence in their own identity and opinions.

Although Kenya has adopted the WHO and UNFPA definition of 'adolescents' as persons aged between 10 and 19 years, a critical challenge when conducting research with adolescents exists because of the lack of the definition of the word "adolescent" in the Legal framework<sup>5</sup>. Individuals are assigned to either "child" or "adult". "Child" as assigned to it in the Children Act 2001 means a person who has not attained the age of 18 years. Although "child" is a person who has not reached the legal age, there are exceptions for emancipated and mature minors.

<sup>5</sup> Children's Act, 2001.

### Guidelines addressing adolescent SRH issues in Kenya

- Kenya AIDS Strategic Framework, 2014
- Population Policy for National Development, 2012
- Kenya Adolescent Reproductive Health Policy, 2015 (under revision)
- National Youth Policy, 2007
- Education Sector Policy on HIV and AIDS, 2014
- National School Health Policy, 2009
- National Guidelines for Provision of Youth Friendly Services, 2005
- Adolescent Reproductive Health and Development Policy Plan of Action, 2005-2015
- National Reproductive Health Policy, 2007

### 1.3: Rationale for participation of adolescents in research

1. Adolescents differ significantly from adults, physiologically and psychologically, as well as developmentally. Their developmental stages influence the limitations and potential benefits of research.
2. Some diseases are found only in children. Given that they are a vulnerable population, research should comply with national ethical and professional norms and legislation, and abide by principles of respect, beneficence and justice, and that which protects adolescents without denying them opportunity for evidence directed interventions. Their involvement in research also requires some justification.
3. Generally, adolescents should only be enrolled in trials when the research question cannot be adequately answered with less vulnerable persons like adults.

It is estimated that more than half of all new HIV infections occur in people younger than 25 years<sup>6</sup>, meaning that adolescents are at risk of HIV infection. Thus, a wide range of effective prevention options needs to be developed for this population. Adolescents differ significantly from adults, physiologically and psychologically, as well as developmentally<sup>7</sup>. Thus, transposition of research conducted among adults onto the adolescents may not be successful. For instance, it has been identified that responses to HIV vaccines may be different in adolescents compared to adults. For example, while product safety may not differ for adolescents, vaccines may be more effective in adolescents at lower or fewer doses than in adults<sup>8</sup>. Some microbicide resource documents have pointed out that adolescent girls differ from adult women, for example, their cervix is not fully mature and they are more susceptible to sexually transmitted infections. Also their menstrual patterns differ; while they may have periods, many younger adolescent girls with irregular cyclical menses do not ovulate, and lower progesterone levels may affect the vagina's immune responses<sup>9</sup>.

While there are important public health reasons to enrol adolescent in HIV research, their inclusion

raises a number of important ethical, social and legal challenges<sup>10</sup>. This population may be subject to multiple forms of vulnerability due to their developmental stage and diminished autonomy, which are often reflected in legal requirements aimed to safeguard them. They include those related to the legal age of consent, consensual sex, and majority as well as legal obligations to report abuse or neglect<sup>11</sup>. Historically, the Nuremberg Code of Ethics of 1947 did not address the participation of children in research. This has seen the twentieth century marked by a number of scandals involving research with children. This includes the 1950-60s Willowbrook hepatitis study, where researchers intentionally infected healthy institutionalized children with hepatitis in order to understand the disease and to develop a vaccine<sup>12</sup>. Issues of ethical concern were raised due to the fact that it was children who were part of the study, with many contending that only therapeutic, and not scientific, medical experiments ought to use children, whilst others contend that parents were blackmailed into consenting. In an attempt to protect children, several guidelines have been established to ensure observance specifically of the rights of adolescents participating in research. However, this safeguard may have effectively excluded them from research, consequently, leading to an unintentional lack of knowledge of development and of appropriate medical treatments for this population in general.

6 It is estimated that more than half of all new HIV infections occur in people younger than 25 years

7 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), Best Practices for Health Research Involving Children and Adolescents, 2012

8 European Medicines Agency (EMA), Ethical Considerations for Clinical Trials on Medicinal Products Conducted with Paediatric Population, 2008

9 G Koren, "Healthy Children as Subjects in Pharmaceutical Research," 2003

10 MacQueen and Karim 2007

11 Friedman Ross. Children in Medical Research: Access versus Protection (New York: Clarendon Press, 2006).

12 MA Grodin and LH Glantz. Children as Research Subjects: Science, Ethics, and Law (New York: Oxford University Press, 1994).



It was not until the 1964 Declaration of Helsinki that inclusion criteria for children were clearly laid out: Guidelines from the Council of International Organizations of Medical Sciences (CIOMS) mention that the participation of minors is indispensable for research concerning diseases affecting infants<sup>13</sup>. Tri-Council Policy Statement (TCPS2) on Ethical Conduct for Research Involving Humans states that inequity is created “when particular groups fail to receive fair benefits of research or when groups, or their data or their biological materials, are excluded from research arbitrarily or for reasons unrelated to the research question<sup>14</sup>.” This reflects an important shift in norms related to research involving adolescents. Today, there is consensus in international ethical norms regarding the need to include children and adolescents in research. However, inclusion of children in research is subject to specific conditions to ensure their protection. Harmony exists among international and Kenyan norms on the following conditions for inclusion of children in research. The guideline for Ethical conduct of biomedical research involving human subjects in Kenya<sup>15</sup> stipulates that:

- Children will not be involved in research that might equally be carried out in adults.
- The purpose of the research is to generate knowledge relevant to the health needs of children.
- A parent or legal guardian must give proxy consent. However, in a situation where the parents or the legal guardian gives permission, but child refuses to participate in the research, that refusal must be respected unless there’s no other medical alternative from which the child could benefit.
- The risk presented by interventions not intended to benefit the child is low and commensurate with the importance of the knowledge to be gained.
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child as any available alternative.

13 Council for International Organization of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects, (Geneva: 2002)

14 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010) at 10 [CIHR, Tri-Council Policy Statement.

15 NCST, 1997

## 1.4: Guiding Ethical Principles

The role of IRBs is to ensure that human participants are protected during research. IRBs should not be seen as a barrier to generating evidence to inform decision making for adolescents health.... As we conduct research with adolescents, let us consider how it will benefit them in the short and long term. If the research is harmful and it is not adding any benefit, then it would be difficult to do that research..... As researchers, engage with IRBs on how to address some of the ethical dilemmas when conducting research with adolescents.”

*Prof Elizabeth Bukusi, Secretary KEMRI National Ethical Review Committee (During stakeholder forum on key considerations for conducting HIV research with adolescents).*

### **Respect for Persons**

Respect for persons requires, as a first step, a determination of whether the potential research participant possesses autonomy, which includes “the ability to deliberate about a decision and to act based on that deliberation”<sup>16</sup>. Respect for autonomy is demonstrated through the informed consent process. If the individual is deemed capable of self-determination, a researcher has the obligations both to provide adequate information about the research and to solicit the individual’s consent to participation. The burden, therefore, is placed on researchers to determine what information is needed and to provide the information in a way that most respects the adolescent participant. Ethically vigorous respect for developing autonomy of an adolescent is shown by informing them about the proposed research and doing so in a manner tailored to the adolescent’s ability to understand, soliciting his or her assent for participation, and respecting dissent<sup>17</sup>.

16 Beauchamp, Biomedical Ethics

17 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

### **Beneficence**

Beneficence obligates the researcher to maximize benefits for individual participant and/or society, while minimizing risk of harm to the individual<sup>18</sup>. In the research context it may be difficult to completely avoid some level of harm or discomfort to participants. Thus, oversee and ensure that participants are protected to the extent possible. In the context of adolescent research, application of beneficence is similar to research involving adults. Research involving adolescents does, however, have different standards for when participation is permissible, illustrating the practical difference between adult and adolescent research. For instance, there must be sufficient justification for the research to be performed on adolescents instead of on adults. Additionally, the risk generally should be minimal. The concept of 'best interest' deserves additional discussion. A competent adult can be expected to judge his or her own best interests – so long as the risk is within accepted bounds. An adolescent, on the other hand, often trusts others to make this judgment. History demonstrates that those who make decisions on their behalf do not always serve the children's best interest. There may be circumstances when parent's/ guardians interests conflict with adolescent's interests. Thus, researchers, parents/guardians and IRBs should be careful that other considerations do not impact a determination of what is in the best interest of an adolescent<sup>19</sup>.

### **Justice**

The ethical principle of justice demands equitable selection of participants and equality in distribution of benefits and burdens among the population groups likely to benefit from the research. It also requires IRBs to carefully consider the necessity of such inclusion and to work with researchers to avoid exploitation. As much as it is unfair to exclude adolescents from research that might benefit them<sup>20</sup>, particular care must be taken to ensure that they are not shouldered with disproportionate or unreasonable risk, especially in light of their vulnerability and general inability to consent to research on their own behalf.

18 Beauchamp, Biomedical Ethics

19 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), Best Practices for Health Research Involving Children and Adolescents, 2012

20 CIHR, Tri-Council Policy Statement

## **1.5 Role of Institutional Review Boards in Research Involving Adolescents**

All protocols involving research with adolescents require IRB approval.

By international practice:

- IRBs reviewing research on adolescents should be multidisciplinary, age and gender-mixed and experienced in adolescents issues
- IRBs reviewing research on adolescents should be trained and sensitized on adolescent related research including evaluation of risk/benefits, quality assurance and monitoring of ethical issues pertaining to research with adolescents
- IRBs reviewing research on adolescents should require additional review mechanisms of research documents (including informed consents, IEC materials, dissemination reports) to ensure they are appropriate to the specific age group of adolescents under study. If possible proof of pilot with adolescents of the same age and literacy capabilities should be required.
- IRBs reviewing research with adolescent through social media should ensure they are trained or seek the support of social media experts to evaluate the security and ethical control mechanisms adequately safeguard the interest of the adolescents.
- IRB members should be offered sensitivity training related to adolescents that may belong to stigmatized or criminalized populations.
- In reviewing protocols on research involving adolescents, important to ensure that any clinical trials have a fully constituted Data and Safety Management Board (DSMB) that will review the protocols and monitor the results of the clinical trials. The DSMB should have the capacity to fulfill its full mandate.

# ETHICAL CONSIDERATIONS

# 2

## 2.1: Developing research protocols on research with adolescents

When planning a study that will involve adolescents it is critical to consider the following main issues:

- Provide scientific justification for including adolescents in the research, including the unique outcomes, benefits, and risks that will come from studying adolescents and that the information to be gained could not scientifically be obtained from adult participants.
- That a goal of the research is to obtain knowledge relevant to the health needs of adolescents;
- How is the study risk level determined? What are the relevant regulations? that the risk presented by interventions having no direct benefit to the individual participant is low and commensurate with the importance of the knowledge to be gained;
- How the study procedures are different from standard of care for the participants.
- Consent (permission and assent) requirements for the study. Will permission from one or both parents be needed?
- Ensure a clear strategy for addressing social harm
- The interventions intended to provide direct benefit are at least as advantageous to the individual participant as any available alternative. Among adolescents, younger participants should not be enrolled when older adolescents are scientifically suitable for recruitment as research participants. When the specific objective of the research is to gain information about young adolescents, then research involving this age group is ethically justified.

- In order to reduce risks to (and increase informed participation of) adolescents in HIV research, it is advisable to include adolescents in community advisory boards (especially young boys and girls at risk of the disease), involve adolescents and parents/caregivers as advisors on recruitment and consent processes, and engage with local youth organizations during the protocol development stage.

## 2.2: Consent, assent, and parental/guardian permission

Informed consent is the process through which researchers respect individual autonomy. An autonomous individual is one who is capable of deliberation and personal choice. With adolescents, research involves more complex considerations with respect to assuring the voluntary participation of research participants than research with adults. There are issues of assent and parental permissions that must be considered.

Voluntary consent of adolescents in research is absolutely essential not only to the safety, protection, and respects, but also for the integrity of the research itself<sup>21</sup>. However, voluntary participation based on valid informed consent is possibly the largest and most complicated issue for researchers working with adolescents. With adults it is normal to use a consent form, or to seek verbal consent. In such cases, if the adult has the capacity to give consent and the research has been adequately explained, then ethically it is easy to proceed. But if it is an adolescent who is under 18

<sup>21</sup> Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

years of age, then they cannot legally give consent themselves and a researcher should ask a parent or guardian for consent. In Kenya, adolescents generally may not consent to medical care or treatment or research involving medical care or treatment, without a parent or legal guardian's consent<sup>22</sup>.

### **2.2.1: Consent process in research involving adolescents**

The process for obtaining oral and/or written consent for adolescents to participate in research is similar to that of obtaining consent for adults. Thus an effective informed consent process for involvement of adolescents in research should involve at minimum these elements<sup>4</sup>:

- Conducting the process in a manner and location that ensures participant privacy,
- Giving adequate information about the study in a language understandable to the adolescent participant,
- Providing adequate opportunity for the adolescent participant to consider all options,
- Responding to the adolescent participant's questions,
- Ensuring the adolescent participant has understood the information provided,
- Obtaining the adolescent participant's voluntary agreement to participate, and
- Continuing to provide information as the adolescent participant or research requires.

### **2.2.2: Assent in research involving adolescents**

Typically, adolescents below 18 years do not have the legal capacity to consent to participate in research, but they should be involved in the process if they are able to assent (i.e., capable of having a study explained to them and/or reading a simple form about it, and giving verbal or written agreement if they decide to participate in the study). "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent<sup>23</sup>. In the context of research involving adolescents, it means that they must actively show willingness to

participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether adolescents are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the adolescents involved. There are circumstances however, in which an adolescent's assent may be unnecessary or inappropriate. They include:

- Research where the capability of some or all of the adolescent is so limited that they cannot reasonably be consulted;" or
- The research holds out a prospect of direct benefit that is important to the health or well-being of the adolescents and is available only in the context of the research

### **2.2.3: Permission from parents/ guardians in research involving adolescents**

Permission is defined as the "agreement of parent(s) or guardian to the participation of their child in research."<sup>24</sup> In most cases, permission from one or both parents/guardians must be obtained for their adolescent to participate in a research study (*See Category of research requiring one parent's or both parents' permission, Table 2*). The IRB should determine that unless parental permission can be waived adequate provisions are made for soliciting the permission of the parent or legal guardian. In certain cases, research may be conducted for conditions or for a population for which parental/guardian permission for inclusion in research is not a reasonable requirement to protect the participants. Circumstances in which parental/guardian permission may be waived include:

- Research on child abuse or neglect, or research that is reasonably likely to elicit information identifying child abuse or neglect, where there is serious doubt as to whether the parents' interests reflect the child's interests.
- Research on adolescent who are under the legal age, but who are in circumstances where they are clearly outside of parental influence or control (emancipated or mature minors).
- Where the parent/ guardian is inappropriate to give consent e.g. in research with adolescent key populations (lesbians, gay, bisexual, trans-gender, men who have sex with men; sex workers and persons using drugs)

22 National Council for Science and Technology. *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*. Nairobi, 1997

23 [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

24 Regulations for the protection of human subjects

### **Exceptions permitting certain adolescents to consent**

Researchers should also be aware that adolescents under 18 who are living independently may not fit the definition of “children” and are able to consent for themselves without a waiver of parental permission. The following apply<sup>25</sup>:

- Research involving emancipated minors
- Research involving mature minors
- Research involving care related to prevention or treatment of pregnancy - an adolescent may consent, but not to sterilization or necessarily abortion
- Research involving adolescents, 12 years or older, seeking care for out-patient mental health treatment or counseling, excluding drugs, care related to the diagnosis or treatment of reportable infectious, contagious, or communicable/sexually transmitted diseases<sup>26</sup>, care provided to the victims of sexual assault or rape, and medical

25 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

26 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

care and counseling relating to the diagnosis and treatment of drug or alcohol abuse (only if treating physician deems and documents that parental involvement is inappropriate), excluding narcotic replacement drugs. For these categories, the IRB should carefully evaluate the research protocol to ensure that the adolescent participant is properly protected. The adolescent should provide consent and sign the consent form just as an adult would, unless the IRB approves a waiver or alteration of the usual consent standards for adults. The process should also be documented in a manner similar to that used to document informed consent for adults<sup>27</sup>. Refer to Box 1 for sample questions and information for investigators seeking waiver of parental permission for adolescent's participation in research<sup>28</sup>.

27 Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

28 Institute of Medicine, *The Ethical Conduct of Clinical Research Involving Children* (2004)

### **Box 1: Questions and information for investigators seeking waiver of parental permission for adolescent's participation**

- Please specify why the research could not be practically conducted without a waiver and why parental permission is not a reasonable requirement.
- Are the risks associated with this protocol minimal? Please specify why.
- The IRB requires assurance that the waiver of parental permission will not adversely affect the rights and welfare of the subjects.
- How will you ensure the privacy and confidentiality of the study subjects?
- Investigators must encourage each adolescent to seek the support of a parent or another adult prior to participation. How will this be accomplished? The informed consent must also address this issue.
- Investigators must establish procedures to allow adolescents to seek assistance on a confidential basis after completing surveys containing questionnaires that may raise issues for which adolescents may desire further information or assistance. Please specify how this will be accomplished.

**Table 1: Consent Requirements for Adolescents by Age Group**

Age of adolescent Participant	Assent Form Recommended	Separate Parental/ guardian Permission Form Recommended	Additional Notes
Adolescents aged 10-12 years old	<b>YES</b> A very simple assent form referring to the adolescent participant throughout as “you.” The child should sign the form if possible. <i>If not, the form or study records must still document that verbal assent was obtained.</i>	<b>YES</b> The form should refer to the adolescent participant throughout as “your child.”	The signature line of the parent’s or guardian’s form should be preceded by an explanatory statement such as: <i>“The person being considered for this study is unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child to participate in the study.”</i>
Adolescents aged 13-17 years old (Option A)*	<b>YES</b> The form should use clear, straight forward language. The form should be based on the Committee on Human research (CHR) sample consent forms, referring to the adolescent participant throughout as “you.” Both the adolescent and the parents or guardians are asked to sign this form, with a signature line for the adolescent first.	<b>NO</b> Add line to adolescent assent form for parent(s) to sign	The signature line for parental consent/permission should follow, preceded by an explanatory statement such as: <i>“The person being considered for this study is legally unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study.”</i>
13-17 years old (Option B)**	<b>YES</b> This adolescent assent form should be simpler than the adult consent form for the same study. (Note that assent forms written for 7-12 year olds are often too simple for adolescents, but can be expanded upon or adapted as appropriate). 2. The form should refer to the adolescent participant throughout as “you.” Only the adolescent is asked to sign this form.	<b>YES</b> A simplified assent form is written for the adolescents. A separate, more detailed permission form is written for the parents or guardians. The separate consent/permission form for the parents or guardians should refer to the adolescent participant throughout as “your child.”	The signature line of parent’s or guardian’s form should be preceded by an explanatory statement such as: <i>“The person being considered for this study is legally unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study.”</i>

\* Option A is usually preferred. One form is written for the adolescent participant and the parents or guardians.

\*\*Reserved for studies where Option A is not feasible or appropriate. Used for studies with a very complex protocol and/or involving adolescent participants whose medical condition demands a simpler form than the adult’s form, even when the adult’s form is written at standard six level (American eighth-grade level equivalent). Sample consent and assent form which can be adapted for use in most studies, using the above guidelines as a basis.

- For adolescents 10 - 12 years (<http://www.research.ucsf.edu/chr/Guide/MNR-assent1-1204F.doc>)
- For more complex study, more mature adolescents (<http://www.research.ucsf.edu/chr/Guide/MNR-assent2-1204F.doc>)
- For adolescents 13 – 17 year (<http://www.research.ucsf.edu/chr/Guide/MNR-assent3-1204F.doc>)

**Category of research requiring one parent's or both parents' permission**

Some situations require permission from at least one parent, while other situations require permission from both parents. The regulations for the protection of human subjects require adequate provisions to be made for soliciting the permission of each child's parents or legally authorized representative or guardian, as summarised below (table 2)<sup>29</sup>.

When parents disagree about allowing their child to participate in the study, the child may not be enrolled unless that disagreement can be resolved. This applies to all permissible categories even if only one parent's signature is required, when both parents are involved in the decision, they must agree for the child to be enrolled. If a parent who was not involved or available for the original consent later becomes involved or available, the two parents must then agree.

**Table 2: Category of research requiring one parent's/guardian's or both's permission**

Category of Permitted Research with Children	Number of Parents' Permission Required
Minimal risk*	One parent/legal guardian may be sufficient
Greater than minimal risk, direct benefit to subject	One parent/legal guardian may be sufficient but IRB must determine whether one or two is required
Greater than minimal risk, no direct benefit to subject, but likely to yield generalisable knowledge about adolescent participant condition	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Greater than minimal risk, no direct benefit to subject, but results may alleviate serious problems of children's health or welfare	Both parents/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

\*The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

### **Other consent considerations for research involving adolescents**

- Consent documents must be clearly written and understandable to participants. The language must be non-technical (comparable to the language in a youth friendly newspaper or general circulation magazine).
- Scientific, technical, and medical terms used in the consent document must be defined or explained in lay terms.
- When enrolling adolescents, related recruitment materials must reflect their reading level<sup>30</sup>.

*[SEE the Informed Consent Lay Language (ICL) database, a comprehensive resource to assist researchers and clinical operations personnel with writing and amending informed consents for study participants. It contains more than 2,200 standardized lay language descriptions of risks and events associated with clinical research<sup>31</sup>.]*

- Informed consent may not include exculpatory language, that is, language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability for negligence.
- The location where the consent is being discussed, the adolescent's physical, emotional and psychological capability must be taken into consideration throughout the consenting process.
- Capacity to consent is related to the nature and complexity of the research. Since the requirements for obtaining informed consent include the provision that subjects be capable of understanding the purpose, procedures, risks, benefits, and alternatives of the research, the participation of adolescents who satisfy this condition is ethically justified<sup>32</sup>.

30 Informed Consent Lay Language database [http://www.nccn.org/clinical\\_trials/informed\\_consent.aspx](http://www.nccn.org/clinical_trials/informed_consent.aspx) SEE the Informed Consent Lay Language (ICL) database, a comprehensive resource to assist researchers and clinical operations personnel with writing and amending informed consents for study participants. It contains more than 2,200 standardized lay language descriptions of risks and events associated with clinical research.

31 Informed Consent Lay Language database [http://www.nccn.org/clinical\\_trials/informed\\_consent.aspx](http://www.nccn.org/clinical_trials/informed_consent.aspx)

32 WHO Ethical issues in Reproductive health involving adolescents. Scientific and Ethical Review Group. [http://www.who.int/reproductivehealth/topics/ethics/adolescents\\_guide\\_ser/en/](http://www.who.int/reproductivehealth/topics/ethics/adolescents_guide_ser/en/)

For adolescent key population requiring parental consent, consent forms need to present accurate information about the study although ensuring privacy for those who have not disclosed their same-sex behavior to their families. They may also be allowed to identify a guardian who has no interest in the research for those requiring consent. This must be documented and IRB notified in the application.

## **2.3: Privacy and Confidentiality**

HIV and SRH health research involves sensitive issues about which adolescents have an interest in, and a right to, confidentiality being maintained. For example, some adolescents may be at risk of physical or psychological harm if others learn that they are sexually active. Moreover, without ensuring confidentiality, some important research cannot be carried out since adolescents may refuse to participate if they are told that information they reveal might be disclosed to others

HIV and SRH research with adolescents involves sensitive issues about which adolescents have an interest in, and a right to, privacy and confidentiality being maintained<sup>33</sup>. Privacy refers to an individual's right to be free from intrusion or interference by others." Thus, the right of privacy is respected when the participant "has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information."<sup>34</sup> In research ethics, confidentiality is a duty that refers to "the obligation of an individual or organization to safeguard entrusted information." This includes the obligations to protect information from unauthorized access use information from unauthorized access, use, disclosure, modification, loss or theft<sup>35</sup>. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project.

33 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010).

34 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010).

35 TCPS Draft 2nd edition: Privacy and Confidentiality (2008). <http://www.pre.ethics.gc.ca/eng/archives/draft-preliminaire/chapter5-chapitre5/>



Important issues of privacy and confidentiality are raised in the specific context of adolescent research. In general, there is agreement that personal information should not be disclosed to third parties without the informed consent of the participant. The table that follows provides a summary of general statement on privacy and confidentiality suggesting a range of safeguards that researchers should implement to ensure the protection of personal information collected during the course of their research with adolescents<sup>36</sup>

**Table 3: Guidance on Privacy and Confidentiality**

Guidance on Privacy and Confidentiality	
<b>Confidentiality</b>	<ul style="list-style-type: none"> <li>• Principal investigator and staff authorized to access an adolescent’s medical, familial, and research files should be identified;</li> <li>• Principal investigator and all members the team are subject to confidentiality both inside and outside research institutions and in the management and communication of data;</li> <li>• Confidentiality also includes persons involved in research who do not have professional status, such as technicians, graduate students and research fellows.</li> </ul>
<b>Access to the Information Collected</b>	<ul style="list-style-type: none"> <li>• Subject to applicable law, access to the information collected in research is dependent on the consent of the competent adolescent or that of the parents if the adolescent is not competent to consent. If feasible, the assent of the incompetent adolescent should be obtained;</li> <li>• Principal researcher is responsible for controlling access to the information collected;</li> <li>• control of this access is similar to the control exercised over delegated medical acts;</li> <li>• those authorized to access such information are under the supervision of the principal researcher;</li> <li>• Adolescents should have access to their information, if feasible (e.g. data is not anonymised);</li> <li>• access may be allowed for monitoring, auditing, review or regulatory inspections;</li> <li>• Researchers should also consider the impact that disclosure of sensitive information to the parents might have on the adolescent (e.g. pregnancy, reports of abuse, substance use) if the parents request access.</li> </ul>
<b>Limits to Confidentiality</b>	<ul style="list-style-type: none"> <li>• The duty of confidentiality is not absolute. Personal information may be disclosed without the consent of the adolescent or parents in some exceptional circumstances, such as abuse or neglect or when notification is required by law.</li> <li>• Moreover, absolute confidentiality may be difficult to ensure in some very special circumstances (e.g. minors suffering from a very rare condition or disease). In this case, even if researchers comply with all the safeguard measures, the disclosure of confidential information of the adolescent may still occur, and the adolescent may be identifiable just by virtue of the rarity of the condition. Therefore, researchers should inform the adolescent and/or parents about this possibility during the informed consent process.</li> </ul>

<sup>36</sup> Centre of Genomics and Policy (CGP), Maternal Infant Child and Youth Research Network (MICYRN), *Best Practices for Health Research Involving Children and Adolescents*, 2012

## Guidance on Privacy and Confidentiality

### Disclosure to Third Parties

- Researchers and members of the research team should never disclose personal information about a participant to a third party unless the competent adolescent consented to such disclosure in writing. If feasible, the assent of the incompetent adolescent should be obtained;
- In exceptional circumstances, and subject to the applicable law, researchers may have an obligation to disclose genetic information to the adolescent's family, despite opposition of the adolescent (whether competent to consent or not), or the adolescent's parents. Three conditions should be met before considering the possibility of disclosure in such circumstances:
  1. non-disclosure could lead to serious and foreseeable harm for members of the biological family;
  2. members of the biological family are identifiable; and
  3. The risk of harm could be avoided by prevention or treatment. In this evaluation, the risk of harm resulting from disclosure should not be greater than the risk of harm to family members from non-disclosure;
- The competent adolescent or the parents if the adolescent is not competent to consent should be informed of the consequences that could result from the disclosure of genetic information. The incompetent adolescent should also be informed, if feasible.
- if non-consensual disclosure is necessary, collaboration with the treating physician or children services (for adolescents under the custody of the government- e.g. orphans, street adolescents) is recommended, where applicable, to encourage discussion with the adolescent and his or her parents about the family follow-up and the consequences of refusing to communicate the information in question;
- Other than in the exceptions by law, no genetic information can be transmitted to insurers, employers, educational institutions, or other public institutions, without the consent of the competent adolescent or that of the parents if the adolescent is not competent to consent. If feasible, the assent of the incompetent adolescent should be obtained;
- In cases where non-paternity is discovered during research, unless it can be shown to be in the immediate and best interest of the health of the child, it should not be disclosed;
- Unless participants consent to the publication of identifiable data and there is a reason to do so, researchers should only publish non-identifying data.

## 2.4: Evaluation of risks and benefits

“Participation of an adolescent in research should offer the possibility of a direct benefit to their health. Where no direct benefit is likely, the results should benefit other adolescents of the same age or with the same disease, exposure, condition or disability, and the adolescent should not be exposed to more than minimal risk”

Although there is consensus among the various ethical norms on the justification for participation of adolescents in research when it holds out the prospect of direct benefit, it is a general rule that the risks should be weighed against the anticipated benefits<sup>37</sup>. The principles of non-maleficence and beneficence impose the ethical obligations to researchers to prevent harm and to maximize possible benefits while minimizing possible harms<sup>38</sup>.

The term “risk” as applied in the research context is “a function of the magnitude or seriousness of the harm, and the probability that it will occur.”<sup>39</sup> The harms can be physical, psychological, legal, social or financial and may affect not only the adolescent being involved in research, but also family, or even community<sup>40</sup>. The term “benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike, “risk,” “benefit” is not a term that expresses probabilities<sup>41</sup>. Research may have a direct benefit for the individual concerned or a benefit for the group to which the individual belongs by virtue of age and medical condition. For example, improvement of the individual adolescent’s health status is a direct benefit, while understanding of the risks of HIV transmission among adolescents is an indirect benefit.

When research does not offer hope of direct benefit to the adolescent, specific requirements apply:

- The proposed research should have a strong chance of contributing to the health of other adolescents in the same age category or with the same disease, exposure or condition<sup>42</sup>.
- The risk should be “reasonable in relation to the importance of the knowledge to be gained.”<sup>43</sup>
- The research should impose no more than “minimal risk” and burden on the adolescent concerned – the risk should be no greater than the risk associated with routine medical or psychological examination or treatment.

Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”<sup>44</sup>. While there is an international consensus on the use of ‘minimal risk’ as a criterion of participation, its practical application lacks precision. Indeed, the criteria of risk comparable to that of “everyday life” and “during a routine medical exam” are not clear. For example, how risks ordinarily encountered in the daily life of an adolescent compare to risks faced in research?<sup>45</sup> Although the answer to these questions is unclear, some procedures have been recognized as being minimal risk, such as a questionnaire, observation, and the collection of urine and blood samples<sup>46</sup>.

The question regarding the participation of healthy adolescents in medical research is also important. There may be need for researchers to make consideration on what types of research may a healthy adolescents participate in, given that they may not be exposed to more than minimal risk and because they would not expect to draw any benefit from the research by virtue of their already healthy status.

37 Best Practices for Health Research Involving Children and Adolescents. 2012

38 Beauchamp, “Biomedical Ethics. 2008

39 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. 2010

40 EMEA, Ethical Considerations for Clinical Trials. [ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/ethical\\_considerations.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/ethical_considerations.pdf)

41 The Belmont Report. [www.hhs.gov/ohrp/humansubjects/guidance/belmont.html](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

42 United Nations Educational Scientific and Cultural Organization (UNESCO) Universal Declaration on Bioethics and Human Rights, (2005).

43 CIOMS, Guidelines 2002; CIOMS, Guidelines 2008

44 Human Subjects Research (45 CFR 46). <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

45 Best Practices for Health Research Involving Children and Adolescents. 2012

46 L Friedman Ross. Children in Medical Research. 2006.

### 2.4.1: Categories of research that may be approved based on degree of risks and benefits

The following table summarizes the four categories of research with adolescents that may be approved by IRBs, based on degree of risk and benefit to individual participants<sup>47</sup>. The information applies to research with adolescents in the context of this guidance document.

**Table 4: Categories of research that may be approved based on degree of risks and benefits**

Category	Requirements
1. Research or clinical investigation not involving greater than minimal risk	Research in this category is approvable provided: <ul style="list-style-type: none"> <li>• Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.</li> </ul>
2. Research or clinical investigation involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects	Research in this category is approvable provided: <ul style="list-style-type: none"> <li>• The risk is justified by the anticipated benefit to the subjects;</li> <li>• The relation of the anticipated benefit to the risk is at least as favourable to the subjects as that presented by available alternative approaches; and</li> <li>• Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.</li> </ul>
3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition	Research in this category is approvable provided: <ul style="list-style-type: none"> <li>• The risk represents adolescent increase over minimal risk;</li> <li>• The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;</li> <li>• The intervention or procedure is likely to yield general knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and</li> <li>• Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.</li> </ul>
4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children	Research in this category is approvable provided: <ul style="list-style-type: none"> <li>• The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children;</li> <li>• The research will be conducted in accordance with sound ethical principles;</li> <li>• Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.</li> </ul>

<sup>47</sup> Best Practices for Health Research Involving Children and Adolescents, 2012

### 2.4.2: Evaluation of Risks and Benefits in Clinical Trials

The acceptance on inclusion of adolescents in clinical trials as a necessity to meet the health needs of this population also acknowledges the varying levels of risk inherent in different phases of clinical trial research. Participation of adolescents in late phase trials (III or IV) is perhaps the most easily acceptable from a risk perspective.

- Generally, by the time a drug has reached these phases of testing, there will be significant data about its toxicity and efficacy in adults to help evaluate the potential risks in minors<sup>48</sup>. Participants in these trials should include only ill adolescents, for whom a higher than minimal risk is appropriate if direct benefit can be anticipated.
- The issue of phase I drug studies deserves special consideration. Addressing the challenge of risk is more difficult for phase I trials than for subsequent phases. These trials will generally, by their nature, have higher than minimal risks and no large likelihood of benefit for the adolescent.
- Since the goal of the earliest trials (phase I) is generally to establish the safety of the drug, there might be little knowledge of the potential harms, nor the likelihood of their occurring. Such risks would prevent the participation of healthy adolescents<sup>49</sup>, although other guidance suggests that there might be circumstances when their inclusion is possible<sup>50</sup>.
- It is important that investigators explicitly state the anticipated risks and document the measures in place to mitigate these risks e.g. counseling for studies that may cause emotional/psychological distress; infection control measures for invasive procedures; referral for treatment if risks cannot be handled within the study setting; provision of standard treatment and care for conditions that may result from participating in the study.

## 2.5: Payment for Adolescents Participation in Research

Research payments for participation in research by adolescents can create opportunities for coercion, especially where a guardian/parent receives money for child to participate in research. International regulations simply underscore that parents cannot be paid for their child's participation in research.

*Best Practices for Health Research Involving Children and Adolescents, 2012*

There are four types of payments to parents/ guardians and the adolescent for their participation in research:<sup>51</sup>

1. Reimbursement - compensates for expenses incurred by their participation, such as transportation, meals and accommodation.
2. Compensation - compensates for time and inconvenience for participating in research.
3. Appreciation - bonus to the adolescent once the research is completed to thank them for participating in research, such as toys, movie coupons, books, computer games.
4. Incentive – to encourage the adolescent to participate in research, such as enrollment incentives).

Reimbursement, compensation and appreciation as payments in research are generally accepted because they do not rise to the level of undue inducement. Incentive payments should be used rarely due to the possibility that they might induce participation without careful consideration of risks<sup>52</sup>. The table that follows provides a summary of key elements of the payment process, considerations when adolescents withdraw from research and considerations for determining payment.

48 Best Practices for Health Research Involving Children and Adolescents, 2012

49 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans , 2010

50 CIOMS, Guidelines 2002; CIOMS, Guidelines 2008

51 D Wendler, JE Rackoff, E Emanuel & C Grady, "The Ethics of Paying for Children's Participation in Research" (2002) Journal of Paediatrics.

52 Best Practices for Health Research Involving Children and Adolescents, 2012

Table 5: Key elements of payment in research

Key elements of payment in research	
<b>Payment process</b>	<ul style="list-style-type: none"> <li>• Type of payment offered should be discussed during the informed consent process;</li> <li>• Payment process should be clearly stipulated in the consent form;</li> <li>• If incompetent adolescent to consent are able to assent, it can be discussed in the assent process as well as in the assent form, when this does not risk exercising undue influence;</li> <li>• When the payment proposed to the incompetent adolescent to consent is an appreciation payment, it may be appropriate to give it as a surprise at the end of the research to thank the child for participation;</li> <li>• Parents should never be paid for the participation of their child in research, other than reimbursement of their expenses and compensation for their time.</li> <li>• Reimbursement for the adolescent maybe given in kind, for example, sanitary towels to girls, educational materials etc (with community engagement in the process of determining the kind of incentive to be provided to adolescents).</li> <li>• In the case of street adolescents /drug users who are adolescents, a feeding program for the whole population should be considered instead of cash.</li> </ul>
<b>Withdrawal of adolescent participant from research</b>	<ul style="list-style-type: none"> <li>• The adolescent should still be entitled to receive the appreciation payment for his/her participation;</li> <li>• If withdrawing for reasons related to a health condition that occurred in the course of the study and payment had been predetermined as a bonus, the parents and the adolescent should be paid as if full participation had taken place. Nonetheless, Adolescents and parents should feel free to leave the study at any time without expecting penalty for their decision (be it for health or non-health reasons such as stigma, change of mind, etc);</li> <li>• The parents/ guardians and the adolescent should be paid in proportion to their participation if they withdraw for other reasons;</li> <li>• Researchers may withhold part or all of the payment if participants are excluded from the research for noncompliance. However, the adolescent should not be denied payment to which they are entitled, due to the non-compliance of the parents/ guardians.</li> </ul>
<b>Considerations when determining Payment</b>	<ul style="list-style-type: none"> <li>• Research should consider what is being paid for (e.g. time, lost earnings, inconvenience, discomfort, expenses related to the research, etc.)</li> <li>• Who will receive the payment: the adolescent, the parents or both?</li> <li>• Will participants be paid equally? <ul style="list-style-type: none"> <li>• How and when will information on payment be disclosed? Will it be disclosed in the consent and, if appropriate, assent process? Or at the end of the research as a surprise? Or after the parents and/or the adolescent have agreed to participate?</li> <li>• What form will the payment take (e.g. money, card, gift, toys)</li> <li>• The payment schedule and the process (e.g. for the reimbursement of expenses)?</li> </ul> </li> </ul>

## 2.6: Research with Adolescents Using Social and New Media

Social media is defined as internet-based platforms and technologies that permit social interaction and facilitate the creation and exchange of user-generated content. Social media research covers all research activities where the information being used is derived from the social media space<sup>53</sup>. Although being an increasing area in research, there is a general lack of guidelines and the danger is that, without a clear, codified, publicly argued framework, adolescent participants are not protected, presenting unique problems and issues involving the protection of human participants.

Specific ethical issues in social media research for adolescents include the following:

**Privacy:** Research ethics regulations express concern over subject privacy in terms of the level of connection of data to individuals, and the potential harm disclosure of information could pose. Principles of research ethics dictate that researchers must ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of any data collected. A violation of privacy or breach of confidentiality presents a risk of serious harm to adolescents, ranging from the exposure of personal, family or sensitive information, to the divulgence of embarrassing or illegal conduct, or the release of data that should otherwise be protected<sup>54</sup>.

**Recruitment:** Researchers are advised to take steps to authenticate participants. For example, investigators can provide each study participant (in person) with a Personal Identification Number (PIN) to be used for authentication in subsequent computer- and internet-based data collection.

**Informed consent:** Given new Internet technologies, tools, and venues, confounding security and confidentiality concerns require attention as they impact informed consent. With adolescents who have not reached the legal age, social media research poses particular challenges to age verification, assent and consent procedures, and appropriate methodological approaches with adolescents. While no formal guidance exists on social media research with adolescents, researchers may apply the following:

- Parental consent may be needed when information is potentially identifiable. Identifiable information makes risks to individuals higher and may mean that the safety net of parental consent is preferable.
- There is also a need to consider whether seeking parental consent would make things worse e.g., by putting an adolescent from a dysfunctional home at risk or result in disclosure to the researcher of additional identifying information about the identity and location of the young person. Parental consent may be “contrary to the best interests” of the adolescent when it offers no protection or makes matters worse<sup>55</sup>.

In addition to the above, it is generally recommended:

- To avoid conducting research that is highly sensitive with adolescents using social media, especially with key populations.
- Security of the platform must be endured and should anything happen that breaches the privacy and confidentiality of the adolescent participants, measures should be put in place to assure their security.
- Need to explore and build up in the area of research with adolescents using social and new media.

53 Social Media Research Guidelines, 2011

54 Internet Research Ethics. Online at <http://plato.stanford.edu/entries/ethics-internet-research/>

55 Spriggs, Merle, 2010. *Understanding Consent in Research Involving Children: The ethical issues*. The Royal Children's Hospital Melbourne, version 4.

# INVOLVING SPECIFIC ADOLESCENT POPULATIONS IN RESEARCH

# 3

## 3.1: Vulnerable Adolescents

Adolescents in general are considered vulnerable because of their inability to make autonomous decisions hence the need to safeguard their interests. In the international community, the term “Orphans and other Vulnerable Children,” or “OVC” sometimes refers only to children with increased vulnerabilities because of HIV/AIDS. At other times “OVC” refers to all vulnerable children, regardless of the cause – incorporating children vulnerabilities by virtue of their family status (for example the orphans, adolescent head of households), economic status (street adolescent or adolescent in street families), their work (adolescents exploited for sex) or sexual minorities (LGBT/MSM) or adolescents using drugs. These are examples of the challenges with vulnerable children hence call for a need for research to inform on interventions. Thus, adolescents in vulnerable situations require additional safeguards to protect their welfare<sup>1</sup>.

In the United States for example, children and adolescents who have been separated from their parents and close family members, including those in the care of agencies, can be included in a study only if it is specifically related to their status (e.g. as separated children); or conducted in schools, camps, hospitals, institutions, or similar settings in which all children are included as participants

The National plan of action for Orphans and Vulnerable Children in Kenya stipulates that the Department of Children’s Services (DCS) shall safeguard the welfare of children and, in particular, assist in the establishment, promotion, co-ordination and supervision of services and facilities designed to advance the well-being of children and their families<sup>56</sup>. It is recommended that use of an independent advocate be applied to represent the views of children when in doubt about the protection provided by their guardians. The advocates background and experience should act in, and agree to act in the

<sup>56</sup> Republic of Kenya. *National Plan of Action on Orphans and Vulnerable Children*. 2008. [www.africanchildforum.org/cfr/policy%20per%20country/kenya/kenya\\_ovc\\_2007-2010\\_en.pdf](http://www.africanchildforum.org/cfr/policy%20per%20country/kenya/kenya_ovc_2007-2010_en.pdf)

### Requirement when considering using an independent advocate

- Permission to seek consent through a child advocate instead of a guardian by the ethical review board.
- Procedures must be determined in consultation with community representatives and consistent with county by laws, regulations and practice.
- A child advocate may act on behalf of a child whose parent is sick or unavailable, but if the parent later becomes able to provide informed consent, their decision must be sought and respected.
- The child advocate must be familiar with the child’s circumstances and be independent of any other interests, including the information gathering activity. For example, an investigator working with children in institutional care may require additional consent from the institution’s director, but an independent advocate is also required to ensure that the child or adolescent’s interests are protected.
- A child advocate may act on behalf of an individual child or adolescent or may represent the interests of a broader group of individual young people within a single activity, depending on the nature of the information-gathering activities.



best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization. His/her role will entail: verification of adolescent's understanding of the assent procedures; supporting the adolescent's preferences; ensuring that participation is voluntary; monitoring reactions; and ensuring adequate follow-up.

Using an independent advocate may be applicable when:

- Adolescents do not have an effective guardian to represent their best interests (for example, adolescents living on the street who are not in contact with their families, or adolescents living in child headed households following the death of their parents).
- There is serious doubt about whether the guardian's interests adequately reflect the interests of the child, for example in the cases of adolescents at risk of abuse within the home. In this case the advocate is responsible for providing informed consent and for upholding protection from harm throughout the activity.

Authentication of guardianship from the local chief as recognized and defined by the community may be necessary in the absence of proof of guardianship as recognized by law.

Death of a parent in the context of HIV has been found as not the only driver of vulnerability. This group of adolescents, who have lost one or both of their parents, and who are hence deprived of the material, social and psychological support of one or more of their primary caregivers<sup>57</sup>, faces even more risks and vulnerabilities than the non-orphans including: Psychological distress due to loss of loved ones, illness in the family, stigma, rejection and absence of adults for guidance, school dropout, engaging in sexual behaviors, rape, and poor appetite. Addressing the needs of children made vulnerable by HIV/AIDS is detailed in PEPFAR Framework for the Protection, Care and Support of Orphans and Vulnerable Children, Living in a World with HIV/AIDS<sup>58</sup>.

57 Schenk, Katie and Jan Williamson. 2005. *Ethical approaches to gathering information from children and adolescents in international settings: Guidelines and resources*. Washington, DC: Population Council.

58 PEPFAR. *Global AIDS Coordinator Orphans and Other Vulnerable Children Programming Guidance for United States Government In-Country Staff and Implementing Partners*. 2006

## 3.2: Adolescents in School

When planning studies involving adolescents in educational settings, investigators should consider the following:

### Obtain support of educational community

- The first step for investigators is to obtain support from the educational community of their target school/adolescents participant group. This may include contacting education officials, the local parents, teachers associations (PTAs) and/or the school principal.
- School officials and/or teachers may approve recruitment for a study, but they do not have authority to give permission for participation of individual adolescent in research—only a parent or guardian, with the child's assent, can do so.

### Active vs. implied consent

- Obtaining "active consent" via permission and assent procedures appropriate for the adolescent participants is required as opposed to "implied consent" (e.g., a child brings home information about participating in a study at school, and absence of response is considered agreement.)

### Offering alternative activities:

- If the study will be conducted during school hours, an equivalent alternative activity should be offered for students who do not wish to participate.

## 3.3: Adolescent Belonging to Specific Populations

Key populations (lesbians, gay, bisexual and transgender, men who have sex with men, sex workers, injecting drug users, and prisoners) are 'key' to both the dynamics of and the response to the HIV epidemic, yet few reproductive health programmes have focused on these groups, resulting in low coverage of interventions, including HIV prevention interventions. Data on adolescent members of key populations in particular are extremely limited; either existing data on these groups are not disaggregated by age, or the research has not been done on adolescent populations, often due to concerns about consent issues or other barriers related to social and legal environments. Key populations, and especially adolescents in these groups, often face significant challenges in accessing

care and treatment due to stigma and discrimination from health providers, and ignorance within health systems about gender variance. In many countries where certain sexual identifications and practices are criminalized, additional barriers are created by individuals' own fears of stigma, abuse, harassment and legal consequences.<sup>59</sup>

Researchers working with key populations in general must abide by ethical guidelines to protect their participants as any other human subjects require protection, additional steps may be required for safe and effective engagement adolescent key populations given the challenging contexts.

For instance, the unintended consequences of research intending to generate knowledge and

evidence on key populations can include heightened stigma and increases in human rights violations, including violence. These realities can shift the ethical balance of costs and benefits, so careful consideration of the potential negative consequences of “minimal risk” scientific research is of special importance in study conception, design, implementation, and dissemination. The guidance document on Respect, Protect, Fulfill – conducting HIV research with LGBT groups by Foundation for AIDS Research (Amfar), Johns Hopkins and IAVI emphasizes the need for even more cautions for confidentiality and security precautions (including consultations with security and legal fraternity) on data and participants when such populations are considered against the law but yet need the same public health tools<sup>60</sup>.

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59 WHO. Adolescent HIV testing, counseling and care. Implementation guidance for health providers and planners. [apps.who.int/adolescent/hiv-testing-treatment/page/key-populations](https://apps.who.int/adolescent/hiv-testing-treatment/page/key-populations)

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60 Amfar, Johns Hopkins and IAVI. *Respect, Protect, Fulfill – conducting HIV research with LGBT*.

# STAKEHOLDERS ENGAGEMENT

# 4

## 4.1: Creating ownership and Support when Involving Adolescents in Research

The need to engage a broad range of stakeholders when conducting any type of study is widely acknowledged. It is generally recognized stakeholder engagement is the creation of relationships with internal and external individuals and groups at the local, national and international levels to ensure cooperation and alignment of interests among parties<sup>61</sup>. Although little systematic guidance on how to engage stakeholders in an effective and efficient way exists, the process draws from the principles of good participatory practice<sup>62</sup>: respect, mutual understanding, scientific and ethical integrity, transparency, accountability, and community autonomy

With adolescent research, stakeholder include adolescents themselves, their parents/guardians, MoH and MoEST offices at County level, children's department etc. It is critical to continuously engage these stakeholders before, during and after research studies. Also important to be aware of the impact of providing too many details that may compromise confidentiality of adolescents. A delicate balance will need to be made in identifying the appropriate stakeholders, appropriate level of information and appropriate level of engagement. The following considerations may be applied in stakeholders' engagement and creating good political and policy environment when conducting research with adolescents:

- Ensure broader community and stakeholder

consultation (especially with adolescents and organizations working on adolescent issues) before initiating the research

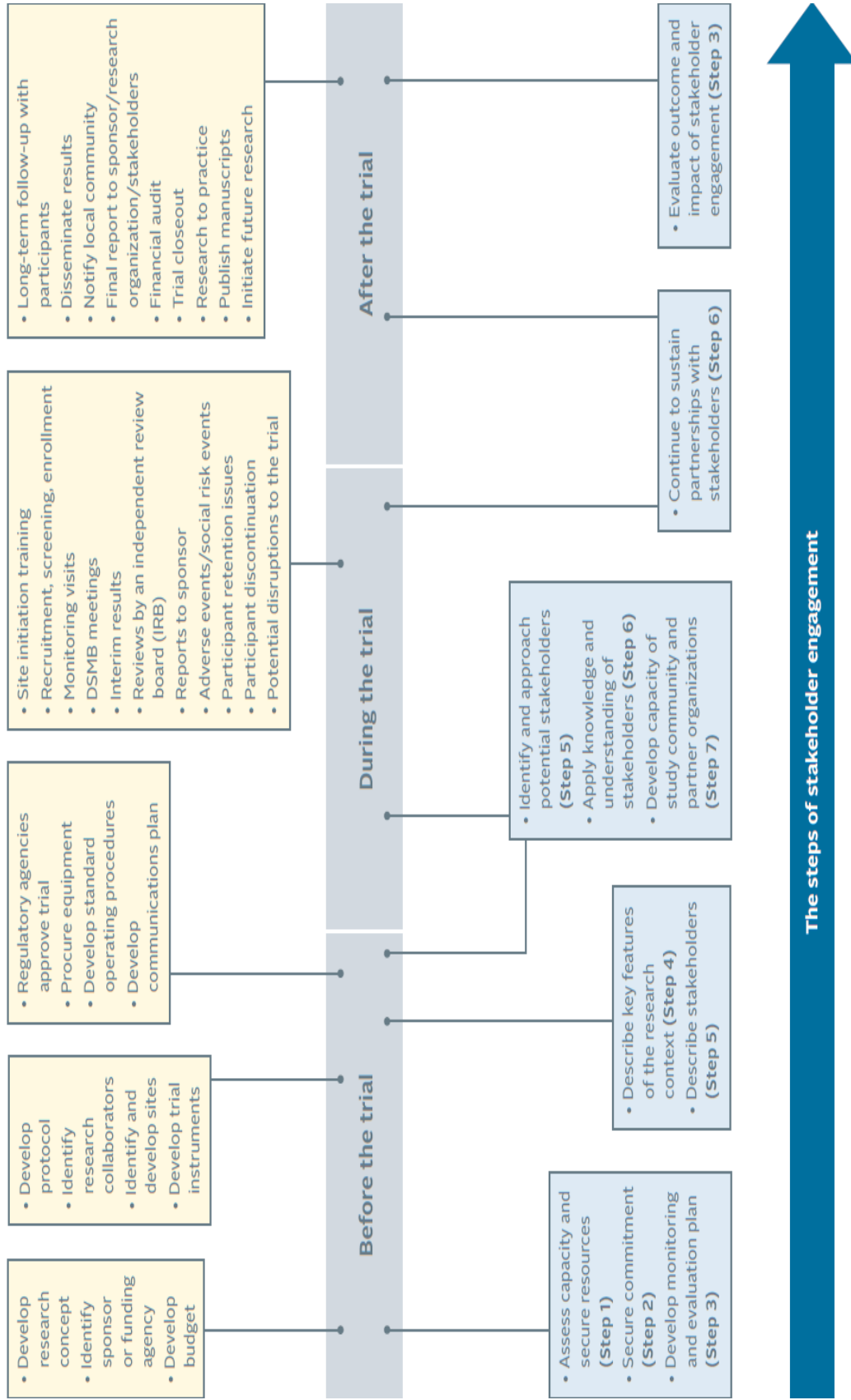
- When appropriate, ensure representation and involvement of adolescents in different processes of the research study.
- Ensure respective MoH and MoEST offices at County and National level are engaged and own the research
- Ensure a comprehensive and culturally sensitive dissemination plan with all stakeholders – including adolescent friendly dissemination tools (in both traditional and new media)
- Provide clarity of study findings and their implications for policy and practice changes – including the benefits to adolescents
- Prepare for crisis-management of potential backlashes with socio-political sectors of the society should findings generate or infringe on existing cultural, religious or political norms.
- Ensure clarity in post-trial access plans should your research prove successful and acceptable by the community and government.

Figure 1 presents a step-by-step matrix on stakeholder engagement to help HIV researchers engage a broad spectrum of stakeholders in an efficient and transparent manner. The recommended processes can also be modified and adopted in protocol development and stakeholder engagement when conducting research with adolescents.

61 FHI360. Stakeholder Engagement Toolkit for HIV Prevention Trials. 2012 [www.fhi360.org/sites/default/files/media/documents/Stakeholder%20EngagementToolkit%20for%20HIV%20Prevention%20Trials.pdf](http://www.fhi360.org/sites/default/files/media/documents/Stakeholder%20EngagementToolkit%20for%20HIV%20Prevention%20Trials.pdf)

62 Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials. Available from: [www.avac.org/gpp](http://www.avac.org/gpp)

**Figure 1: Step-By-Step Matrix on for Developing Protocols and Stakeholder Engagement in research with adolescents**



Source: FHI360. Stakeholder Engagement Toolkit for HIV Prevention Trials, 2012

# RECOMMENDED RESOURCES

National Council for Science and Technology. *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*. Nairobi. 1997

UNAIDS/WHO guidance document. *Ethical considerations in biomedical HIV prevention trials* 2012.

U.S. Department of Health and Human Services, Office for Human Research Protections. *Special Protections for Children as Research Participants*.

National Institutes of Health (NIH). *Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects*

Institute of Medicine, *The Ethical Conduct of Clinical Research Involving Children* (2004)

Sugarman J. *Determining the appropriateness of including children in clinical research*. JAMA 2004; 291(4):494-496.

Wendler D, Rackoff JE, Emanuel EJ. *The ethics of paying for children's participation in research*. J Pediatrics 2002; 141(2):166-171.

Dorn L, Susman E, Fletcher J. *Informed consent in children and adolescents: age, maturation and psychological state*. J Adolesc Health 1995; 16:185-190.

DHHS Regulations and Guidance

- 45 CFR 46, Subpart D: *Additional Protections for Children Involved as Subjects in Research*
- 45 CFR 46.408(c): *Requirements for Permission by Parents or Guardians and for Assent by Children*
- OHRP, *Protecting Human Research Subjects Guidebook* (1993) Chapter 6, Section C, Children and Minors.
- OHRP Children's Special Issues Page
- OHRP Research with Children - FAQs

FDA Regulations and Guidance

- 21 CFR 50, Subpart D: *Additional Safeguards for Children in Clinical Investigations*

UCLA OHRPP Guidance

- *Research Involving Children and Minors*

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<b>HIVOS</b>	Ruth Kimani	<b>Population Council</b>	James Matheka, Tabitha Gitau
<b>KNH</b>	David Bukusi, Margaret Musundi	<b>AIDs Law Project</b>	Terry Rotich, Joy Muthoni, Maureen Milanga
<b>Africa Alive</b>	Georgina Obonyo, Julian Onyango	<b>National Youth Centre</b>	Silas Rabah
<b>DSW</b>	Jessie Mugambi, Nicholas Shiatenya	<b>Global Communities</b>	Lily Murei
<b>KMYA</b>	Fatuma Juma	<b>Nembu Girls High School</b>	Susan Njeri, Betty Obondo, Ernest Micheni
<b>HERAF</b>	Beatrice Gachambi, Lumasia Karani	<b>LEPTA Community</b>	John Ngari
		<b>Women Challenged</b>	Elizabeth Gichohi
		<b>University of Manitoba</b>	Grace Gakunji
		<b>Ecomedia</b>	Conrad Mudibo





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