



VOICE: HIV Youth Informed Consent & Ethics in Research

A Consensus Statement on Improving Adolescent and Young Adult Informed Consent in HIV Research in Low- and Middle-Income Countries



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“*If the structure does
not permit dialogue,
the structure must be
changed.*”

- Paulo Freire

Contents

Executive Summary	1
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Consensus Statement	2
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Improve education about HIV and research processes	2
Enhance AYA engagement in the research process	2
Make research participation more AYA-responsive	2
Empower AYA and local communities	2
Enhance the involvement of parents/guardians in the research process	3
Develop institutional and policy level strategies	3
Enhance engagement with other key stakeholders	3

Acknowledgements	4
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Resources	6
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Annex 1	6
Annex 2	7

Executive Summary

Adolescents and young adults (10–24 years old, AYA) have considerable experience and wisdom that has been neglected in global HIV programs and research. This lack of voice and related marginalization likely contributes to worse HIV outcomes among many AYAs in low and middle-income countries (LMICs). More AYA HIV research is needed, but unique ethical, social, structural, and legal challenges with obtaining AYA informed consent discourage research participation. Parental permission requirements and other challenges have resulted in systematic AYA exclusion from HIV prevention and treatment studies.

We organized a scoping review, a crowdsourcing open call, and an adapted Delphi method to develop a consensus statement to improve AYA informed consent in LMIC HIV studies. The process was organized by the Adolescent Bioethics Working Group of the NIH PATC3H Research Consortium in partnership with 4YouthByYouth (an AYA-engaged research program), the Nigerian Institute of Medical Research, and the Adolescent HIV Treatment and Prevention Implementation Science Alliance. AYA were included in the governance (steering committee, judging panels), generation of ideas (open call participants), refinement of the draft statement (online working group), and finalization of the consensus (consensus participants).

The consensus statement provides practical strategies to improve AYA informed consent in HIV research. We focus on HIV specifically, but many of the issues raised here are relevant to sexual and reproductive rights. The goal is to improve AYA-driven participation in HIV research by improving informed consent. These need to be considered in the local legal context. The intended audience is research ethics committees, AYA advocates, HIV researchers in LMICs, policymakers, advocacy leaders, funders, institutional officials, and others interested in AYA HIV research.

Consensus Statement

Improve education about HIV and research processes

1. Develop AYA-focused informational and communication materials on HIV and research processes tailored for a range of stakeholders (e.g., AYA, parents/guardians, communities, policy and ethics committees, community leaders, etc.), and co-create these materials with AYA.
 2. Engage a broad range of stakeholders (e.g., AYA, religious leaders, community/traditional leaders, parents/guardians) in disseminating information and communication about HIV and research.
-

Enhance AYA engagement in the research process

1. Include AYA as active members of the research team, from conceptualization through to dissemination, prioritizing populations most affected by HIV in line with the research focus.
 2. Build the capacity of AYA to review protocols, and develop strategies to involve AYA in reviewing AYA-focused protocols in order to give them a voice in the space of ethics review; where possible, include AYA as members of ethics committees.
 3. Tailor recruitment methods for AYA, driven by their input and involvement.
 4. Facilitate informational and social support to enhance AYA capacity for autonomous decision-making in consent, with consideration of the risks and benefits involved in the study.
-

Make research participation more AYA-centered

1. Use AYA-responsive language defined by local AYA.
 2. Ensure privacy and confidentiality for AYA to participate in research.
 3. Give choices for informed consent such as paper-based, digital when feasible, and/or other options.
 4. Parental involvement in their AYA's participation in research is encouraged whenever possible, but when not feasible or safe, alternative consent methods that incorporate appropriate sociocultural, ethical, and legal contexts to provide added safeguards may be considered (e.g., legal guardian, trusted adult advocate, ombudsman, legal emancipation).
 5. Ensure appropriate AYA compensation for research.
-

Empower AYA and Local Communities

1. Raise awareness among research ethics committees that many AYAs, especially those aged 15 and above, can make independent decisions about informed consent.
2. Support AYA to advocate for program and policy change that impacts AYA.
3. Build capacity for AYA-driven research through co-creation.

4. Establish formal mechanisms for AYA engagement in research such as co-creation, crowdsourcing, or youth advisory board.
 5. Build capacity for AYA-responsive demand generation and recruitment processes.
 6. Develop adult researcher allies to cultivate AYA-responsive informed consent and ethical conduct of research.
 7. Disseminate research findings in ways that are AYA-responsive.
-

Involve parents/ guardians in the research process

1. Enhance dialogues between AYA and the older generation in HIV research.
 2. Encourage parental/guardian involvement in HIV research where safe and appropriate.
 3. Enhance participatory community outreach with parents/guardians and other community leaders.
-

Develop institutional and policy-level strategies

1. Foster a coalition of youth and researchers to engage research policymakers for regulatory changes to enhance youth participation in HIV research.
 2. Consult with AYA on institutional and policy facilitators, barriers, and opportunities in regard to AYA research participation
-

Enhance engagement with other key stakeholders

1. Policymakers and researchers should establish long-term community engagement plans with multiple stakeholders.
 2. Facilitate research education in academic institutions to promote research literacy.
-

Acknowledgment

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Resources

Annex 1: Glossary of terms

Term	Definition
AYA	Adolescent and Young Adults between the ages of 10-24 years
AYA-responsive	An evolution from adolescent-friendly approaches towards a system of approaches that focus on the needs and preferences of AYA based on demonstrated effectiveness or driven by responses from local AYA.
Co-creation	The collaborative involvement of AYA in decision-making related to research design, implementation, monitoring, and dissemination.
Crowdsourcing	A group of people solve all or part of a problem and then share back solutions with the community.
Compensation	Money awarded to AYA in recognition of their contribution to an idea or service.
Engagement	Different mechanisms for AYA to express opinions and have a voice in the decision-making and implementation processes of research or projects that affect them.
Participation	The action of taking part or becoming involved in research processes.
VOICE	<u>HIV Y</u> outh <u>I</u> nformed <u>C</u> onsent and <u>E</u> thics in Research

Resources

Annex 2: English Language Open Access Resources on AYA consent

→ [Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents](#)

This report by the World Health Organization makes recommendations on challenging ethical aspects of youth sexual health research, including consent and autonomy (Chapter 2). The intended audience is researchers, ethics committee members and sponsors involved in sexual and reproductive health research.

→ [Ethical issues in adolescent HIV research in resource-limited countries](#)

This article discusses important ethical standards in conducting youth HIV research in low- and middle-income countries. It addresses some of the challenges commonly encountered in these settings, such as conflicting ethical and legal guidelines, and provides a set of benchmarks for meeting ethical principles.

→ [Inclusion of Adolescents in STI/HIV Biomedical Prevention Trials: Autonomy, Decision Making, and Parental Involvement](#)

The authors examine the current legal and ethical requirements governing youth participation in sexual health research, from a U.S. perspective. The authors distinguish between consent for clinical care and consent for research participation, and discuss the corresponding guidelines for these different scenarios. A list of practical considerations for youth participation in research studies is provided.

→ [Advancing independent adolescent consent for participation in HIV prevention research](#)

This editorial summarizes questions that were posed at the 2015 US National Institutes of Health workshop that focused on scientific, ethical, and legal challenges with obtaining independent consent for youth to participate in HIV research (i.e. youth providing their own consent for participation, rather than a parent/guardian).

→ [Inclusion with protection: obtaining informed consent when conducting research with adolescents](#)

The UNICEF brief explains the importance of including young people in research and the need to balance inclusion with protection. It gives a history of the legal regulations surrounding youth consent to research participation. Current research in psychology and neuroscience is used to evaluate the capability of young people to provide informed consent. Some recommendations are provided for alternatives to parental consent.

→ [Using the concept of parental responsibilities and rights to identify adults able to provide proxy consent to child research in South Africa](#)

This article examines the question of whether and how to identify an appropriate adult who can provide informed consent in place of young person's parent or legal guardian. The authors argue that there are instances in which the power to provide proxy consent for younger children should be conferred to caregivers by ethics committees, where parents or legal guardians are unavailable. However, the authors note that this should take place only under specific circumstances, including low-risk studies and studies that do not involve a clinical trial.

→ [Adolescent participation in HIV research: consortium experience in low and middle-income countries and scoping review](#)

This article is written by the PATC3H Adolescent Bioethics Working Group. The article summarizes the ethical and legal challenges with youth participation in HIV research, and describes the requirements for obtaining youth consent to HIV research participation in seven countries: Brazil, Kenya, Mozambique, Nigeria, South Africa, Uganda, and Zambia. Three potential solutions are proposed for consent strategies that may help to increase the inclusion of young people in HIV research: independent consent, waiving parental/guardian consent, and surrogate decision makers.

→ [Assessing and supporting adolescents' capacity for autonomous decision-making in health-care settings](#)

This WHO report for health care professionals provides guidance on how to assess and support adolescent decision making in clinical settings. The primary audiences are clinical health professionals in adolescent clinics, policy-makers, and AYA advocacy organizations.

→ [Clinical research in resource-limited settings: Consensus statement from the Council for International Organizations of Medical Societies](#)

This consensus statement developed by the Council for International Organizations of Medical Societies describes information about organizing clinical research studies in LMICs, including ethical issues and community engagement. Primary audiences are LMIC researchers, policy-makers, and health professionals.

→ [We Matter, Value Us: A Guideline for Organizations on the Meaningful and Ethical Engagement of Young People Living with HIV in the HIV Response](#)

The Global Network of Young People Living with HIV (Y+ Global) created this guideline for organisations to work in partnership with young people living with HIV. The guideline focuses on how to engage youth in a meaningful and effective way. The primary audiences are youth organizations, government agencies, implementors, and media.

→ [Quality standards for adolescent participation in clinical research decision making](#)

Penta developed this list of standards for youth (0-18 years old) participation in clinical research decision making. This includes indicators for research studies focused on youth. The primary audiences are youth research funders, youth researchers, and youth research staff.

→ [Youth 2030: Working With and For Young People](#)

This document developed by the UN focuses on youth (15-24) as positive enablers of change. The main audiences are policymakers, national leaders, regional and global influencers.



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