

# The Development of Quality Standards for the ethical and meaningful participation of children and young people in clinical trials and research

Authors: Burke, T; Conway, M

## The background

Article 12 of the UN Convention on the Rights of a Child states children have 'the right to freely express their views on all matters' and for these to be given 'due weight' (1)

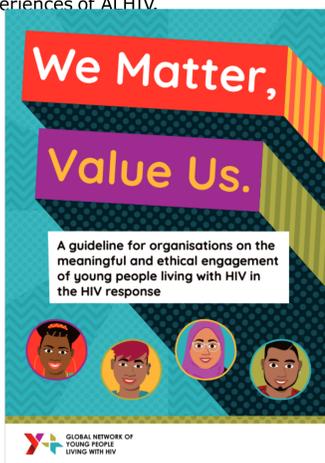
Paediatric HIV clinical research seldom engages children (0-18 years) in its development and delivery. Adolescents living with HIV (ALHIV) are often disengaged with the science relating to their condition, which in-turn impacts on their ability to self-management as they transition to adulthood.



Canvas from 'Sun & Petals' series, by Emanuele Tasca

Fondazione Penta ONLUS (Penta) has been developing and improving a model of engaging ALHIV in research since 2017; however engagement of ALHIV across the research space remains minimal.

As the **Global Network of Young People Living with HIV** (Y+ Global) began a process to create ethical engagement guidelines, '**We Matter, Value Us**' (1), it was felt that something similar should be produced to not only support youth engagement in research, but also ensure this engagement is ethical, progressive, safe and reflects the experiences of ALHIV.



## The process

Key stakeholders were invited to an initial conversation to explore the idea of creating Standards for the sector to support better, more inclusive and ethical engagement of ALHIV in research conducted about them.

Through this meeting, those attending organically became a Steering Group for the Standards, with representatives from:

- ★ Adolescent Treatment Coalition (ATC)
- ★ Collaborative Initiative for Paediatric HIV Education and Research (IAS)
- ★ connect4children
- ★ Elizabeth Glaser Pediatric AIDS Foundation
- ★ Global Network of Young People Living with HIV
- ★ Paediatric and adolescent HIV clinical trials representatives: Trial managers, Primary Investigators, Trial Communication Specialist, Social Scientist
- ★ ViiV Healthcare
- ★ World Health Organization (Paediatric & Adolescent HIV team)
- ★ Zvandiri, Africaid

ALHIV from multiple countries were engaged in the development process through four workshops that ran at different stages of the process. Due to COVID-19, these had to be conducted virtually, but this allowed for multi-country discussion, which included breakout rooms facilitated by coordinators in local languages.



Photo of YTB-UK meeting 2018

A desktop review was conducted on current Standards for engaging children and young people, specifically focusing on health. 37 documents were located and reviewed, with the findings presented to the Steering Group. This process supported learning and enabled discussion how necessary new Standards would be and what format they should take.

Key stakeholder interviews were conducted with 11 people involved in research and/or youth engagement. This was used to gain a better understanding of the structures of global research, research institutions, the roles and responsibilities of those involved in research (specifically clinical trials) and explore what areas the Standards needed to address.

An intensive editing process allowed multiple people from different disciplines' and ALHIV the opportunity to go through the Standards at different stages of their development and offer guidance and suggestions.

## What we learnt

Current guidance and standards on patient involvement did not meet the needs of those running Paediatric HIV clinical research.

There was a strong desire for concise, clear and accessible standards to ensure patients' voices are part of research design and delivery. At no point was anyone against the development of these, but concerns were raised on the need for guidance to be user-friendly, accessible, relevant and be able to effect the change needed.

The Standards need to have the capacity to offer guidance to both small-scale projects through to large, multi-trial institutions. They must be progressive, aiming for higher engagement and power sharing, through a process of building foundations of good quality engagement and then guidance on how to build on this.

They need to be accessible to someone who has never attempted to engage adolescents in their research, through to those who this is their profession. The Standards need to reflect that practice should be evolving and improving, listening to what adolescents say and acting upon this.

The Standards need to cover all considerations about working with children and adolescents, such as safeguarding; reward/recognition of participants' time; and ensuring that all costs are covered. Only by doing this can the work be done safely and ethically.

Initially there was a standard developed for Research Ethics Committees. It was acknowledged by all that this is an important group who can both hold research accountable to ensure engagement of adolescents, and who would benefit from themselves involving adolescents in the review process for research. But as only one person involved was part of an REC, it was felt that additional work needed to be done to engage REC's in a process to develop their own guidance. To that end, this was removed for the core Standards, but is included in Appendix A: REC's roles in supporting adolescent participation.

Although the process undertaken was intensive, it highlighted the size and complexity of the community these Standards need to reach. It became clear that to ensure these Standards were user-friendly and meet the needs of the various audiences, it would be best to divide them into focused areas and after publishing them, keep them 'live' and monitor responses from those implementing them., so that further changes can be made should they be needed.

## Quality standards for adolescent participation in clinical research decision-making.

Published in July 2022, the completed Standards are now available on the Penta website: <https://penta-id.org/patient-involvement-quality-standards/>



Photo by Choregraph from Getty Images

There are **32 Standards** in total, that are divided into four categories to reflect who would be responsible for and oversee the implementation of these particular Standards.

The categories are:

**Funders** - those providing funding for a particular clinical research project or who contribute to core costs of a clinical research centre.

**Research centre leadership** - those responsible for the governance, leadership and management of research centres.

**Research project leadership** - those responsible for the executive leadership of a specific research project.

**Staff responsible for participation** - those staff with defined roles and responsibilities for the planning, delivery and evaluation of participation activities with adolescents



Photo by Alexander's Images from Canva

Each set of Standards covers **five areas** of the research lifecycle:

**Institutional and governance issues:** relate to structural issues that must be considered for effective participation: strategy, staffing, policies and procedures, safeguarding, etc.

**Setting a research agenda:** relate to how adolescents influence the scope and agreement of research topics and general lines of enquiry.

**Plan and design:** relate to how adolescents influence the design and planning of research.

**Delivery and management:** relate to how adolescents influence the implementation of research projects.

**Reporting of results:** relate to how adolescents receive information about, and how they influence the dissemination of, the substantive results from research project(s).

Each Standard has **three different levels** of indicators that the Standard is being met:

**Primary:** this is the minimal level of practice required. These indicators show that the basic components of quality participation are being met.

**Secondary:** these seek to ensure that adolescents have increased influence in decisions that affect them and that they have access to more information or are involved in a broader range of topics for decision-making.

**Tertiary:** these seek to increase the autonomy of adolescents within the research.



Photo - parent and child at HIV camp

## Conclusions

Through an extensive consultant process, a set of Standards have been developed to support adolescent participation in clinical research decision-making.

There are 32 Standards for four groups of people involved in research: Funders, Research Centre Leadership; Research Leaders; Staff responsible for the participation of adolescents.

Although these Standards were developed primarily with and for the HIV research sector, they are not HIV specific and can be used in any research setting involving children and adolescents.

To ensure these Standards are usable and useful, they will remain 'live'. Penta would be happy to work with organisations and researchers to support their implementation and evaluate the effectiveness of the Standards.

Ensuring adolescents have a voice in the research is at the core of mantra, '*Nothing About Us, Without Us*'.

Historically this group have been absent from the development and delivery of research, but it is hoped that by setting out clear structures to support their safe and ethical engagement, this generation of adolescents living with HIV will be able to engage with the science of their healthcare provision.

**Rather than following the science, ALHIV will be equal partners in the development and delivery of the science.**

## References:

- (1) UN Commission on Human Rights, Convention on the Rights of the Child., 7 March 1990
- (2) We Matter, Value Us. (Y+ Global, 2022) <https://www.yplusglobal.org/resources/we-matter-value-us-ethical-engagement-guideline>

**Fondazione Penta ONLUS** (Penta) is a leading international research organization in paediatric infectious disease (<https://penta-id.org/>).



## THANK YOU

Many individuals and organisations were involved in the development of these standards. Special thanks to: Dr Anna Turkova (CTU, MRC London); Annabelle South (CTU, MRC London); Begonya Nafria Escalera (Institut de Recerca Sant Joan de Déu); Cosima Lenz (EGPAF); Daren Paul Katigbak (Y+ Global); Dr Sarah Bernays (University of Sydney); Prof. Gareth Tudor-Williams (Imperial College London); Julian Kerbogossian (Adolescent treatment Coalition); Lindsey Hunter (Penta); Dr Lionel Tan (ViiV Healthcare Ltd); Lungile Jafta (Penta); Mags Thomason (CTU, MRC London); Marissa Vicari (CIPHER, IAS); Mercy Shibemba (Penta); Nicola Willis (Zvandiri, Africaid, Zimbabwe); Dr Serufusa Sekidde (ViiV Healthcare Ltd), Shabinag Ali (CTU, MRC London); De Wole Ameyan (WHO).

All the adolescents and young people living with HIV who were involved in the workshops and ensured these Standards reflected their experiences and needs.