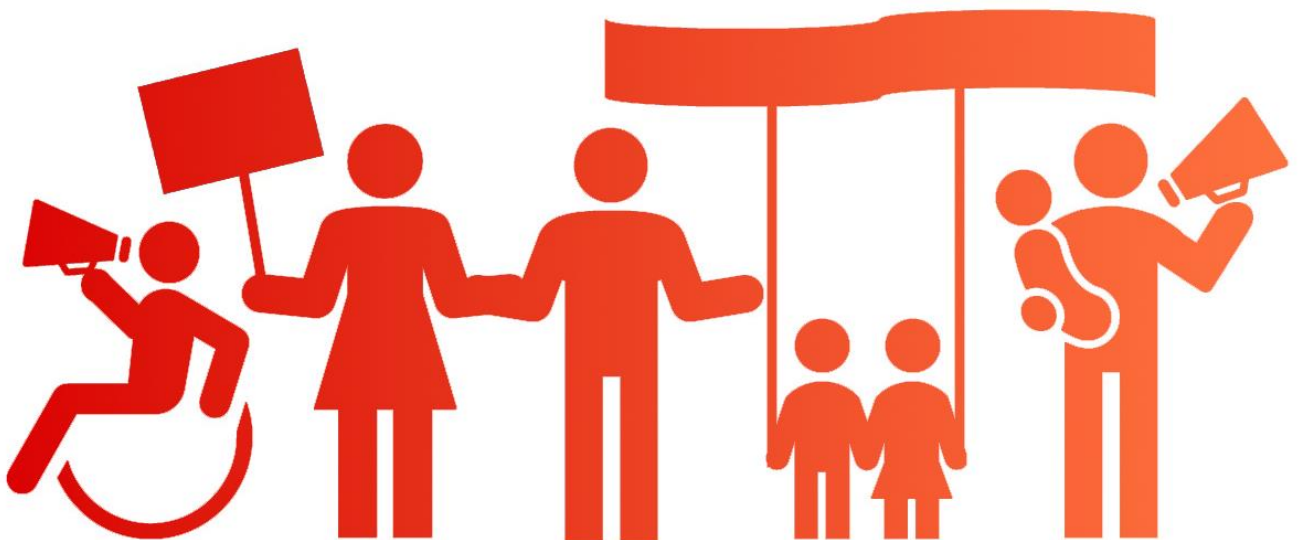


Quality standards for adolescent participation in clinical research decision-making

Tom Burke and Magda Conway
2022



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1.

INTRODUCTION

About these standards,
their development and how
to use



Introduction and background

“Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results.”
International Ethical Guidelines for Biomedical Research Involving Human Subjects

There are a range of ethical standards for medical and health care research projects involving people. These have increasingly included expectations of how the clinical research participants or the wider public can influence research projects.¹

These wider ethical standards sit alongside the rights of children to participate in decisions which affect their lives. The UN Convention on the Rights of the Child is the world's most widely ratified human rights instrument. It ensures that all individuals aged 17 and under who can form views have the right to express those views freely in all matters affecting them, and for those views to be given due weight in accordance with their age and maturity.

What is adolescent participation?

There is no universal definition of participation. It is sometimes called engagement or involvement. Broadly,

Why these standards are needed

Penta has developed a range of activity on patient and public involvement. As part of the ODYSSEY trial - a multi-centre, randomised clinical trial reaching children and adolescents with HIV – we developed pilot ‘Youth Trials Boards’. The project developed an interactive, youth-friendly, activity-based training programme with young people living with HIV across four different

it is about ensuring that research is carried out ‘with’ or ‘by’ patients and/or members of the public rather than ‘to’, ‘about’ or ‘for’ them. For the purposes of these standards, participation can be defined as the process by which individuals and groups can influence decision-making and bring about change.²

More specifically, adolescent participation allows adolescents an appropriate space to form an opinion; to voice their opinions; have an audience which listens to them and, eventually, to influence decisions.³

The United Nations Committee on the Rights of the Child monitors the implementation of children’s rights. It describes participation as the ongoing processes, which include information-sharing and dialogue between children and adults, based on mutual respect, in which children learn how their views and those of adults are taken into account and shape the outcome of such processes.⁴ The Committee has stated there are nine basic requirements for participation. Any participatory process needs to be:

Further details of these requirements are found in Appendix C.

- Relevant
- Voluntary
- Transparent and informative
- Safe and sensitive to risk
- Respectful
- Child friendly
- Supported by training
- Accountable
- Inclusive

countries (Uganda, Zimbabwe, South Africa and the UK). As part of the project, a literature review found significant barriers to the participation of children and young people in decisions made about research which affects them. The project concluded that there was a lack of clear standards for what effective, meaningful and ethical participation is, and what ambition power sharing with young people would look like in practice.

¹ See for example, Council for International Organizations of Medical Sciences / World Health Organisation (2016) [International Ethical Guidelines for Biomedical Research](#)

² Adapted from Treseder, P. (1997) Empowering Children and Young People: Promoting Involvement in Decision-Making Save the Children.

³ Lundy, L. (2007) ["Voice" is not enough: conceptualising Article 12 of the United Nations Convention on the Rights of the Child](#) British Educational Research Journal Vol 33 (6) pp. 927-942

⁴ UN Committee on the Rights of the Child GENERAL COMMENT No. 12 (2009) [The right of the child to be heard](#)

In September 2020 Penta secured funding from ViiV Healthcare to build on the success of the Youth Trials Boards, allowing for the model to be embedded in large clinical research hubs. The standards were part of this funding, developed to compliment the continuing development of these Boards and share learning for practice more widely.

Alongside the developments of practice at Penta, there has been a growing recognition of young people playing an active role in research which affects them. Yet, ethical scrutiny of their participation in projects can vary hugely.⁵ Young people themselves have been calling for organisations to ensure that the ways they are involved in decisions and treated by organisations improved to avoid young people feeling unsupported, exploited, or used.⁶

Development of quality standards

These standards have been developed following consultation and engagement with researchers, patient and public involvement practitioners, policy makers, funders, youth participation practitioners and advocates, and adolescents themselves. A project steering group met at the inception of the project and several times during the development of the standards to offer advice, guidance and direction regarding their

form and content. The standards were developed through various activities, which included:

- Interviews with practitioners and policy makers to explore user needs and the content of the standards
- Mapping of 37 standards frameworks across youth participation and clinical research
- Five consultation events with young people from the United Kingdom, Uganda, South Africa, Zimbabwe and the pan-African network of youth activists engaged with the Elizabeth Glaser Pediatric AIDS Foundation
- Circulation of draft standards for comments and feedback.

We hope that the standards contribute to sharing power with adolescents in decision-making in clinical research. The following standards do not reflect current dominant practices in clinical research involving adolescents but aim to purposefully increase the scale, breadth and quality of their participation in decision-making. Therefore, we anticipate that as the practice and experience of adolescent participation in clinical research develops, these standards may also evolve. We welcome any feedback regarding the standards, their use, and how they can be further developed.

⁵ C.f. Hagell, A and Benniche, S (2022) [Engaging young people in health services research and service design: Key constructs and ethical challenges](#). Association of Young People's Health

⁶ C.f. The Global Network of Young People Living with HIV (Y+ Global) (2022) [We Matter, Value Us. A guideline for organisations on the meaningful and ethical engagement of young people living with HIV in the HIV response](#)

About these standards



What are these standards?

These standards set minimum requirements to involve adolescents ethically and meaningfully in decisions that affect them throughout the design, delivery, and implementation of clinical research.

These standards ensure that adolescents:

- are informed of their right to be heard
- receive appropriate information to help them form their views
- have opportunities to share their views
- take part in inclusive, safe, appropriate and effective processes which treat them with dignity and respect and values their contribution
- are aware their views are valued and given due weight in decision-making
- are informed of what's changed due to their participation
- can hold organisations and staff accountable for decisions and activity.

The standards are divided into four parts – each related to a different group engaged in clinical research.

Appendix A gives information on the role of Research Ethics Committees in supporting adolescent participation. Appendix B defines Key Terms used in the standards.

What is the purpose of the standards?

These standards bridge the gap between the knowledge and experience of youth participation advocates and practitioners and those leading medical and healthcare research projects which aim to improve adolescents' lives.

These standards intend to increase the scale, breadth and quality of adolescent participation in clinical research. Through adoption of the standards, we hope to see:

- more adolescents having opportunities to influence clinical research which affects their lives (scale);
- adolescents having greater influence on decisions made within clinical research – both in the context of specific research projects and within the organisations that fund, design, and deliver clinical research (breadth);

- participation activities in any aspects of clinical research that are more effective, ethical and meaningful (quality).

Which groups do the standards seek to support the participation of?

The standards have been primarily developed for adolescent participation. The World Health Organisation defines “adolescence as the phase of life between childhood and adulthood, from ages 10 to 19 years-old”.⁷

As adolescents grow, they gain competencies and the capacity to express a view and take responsibility for decisions affecting their own lives. At the same time, there is a reduced need for direction and guidance from parents or other adults who are responsible for them. Individuals in different environments and cultures who are faced with diverse life experiences will acquire competencies at different ages, and their acquisition of competencies will vary according to circumstances.⁸

These standards, therefore, set a framework for considering participation but will need to be adapted to specific adolescent groups that are being engaged, as well as the level of support provided to enable them to access information; to form and express a view; and the complexity of the decision which they are influencing. The standards may be tailored to various age ranges to focus on younger or older adolescents, children aged 9 and under, or people aged 20 and above.

Who should use the standards?

These standards are intended to be used by all parties involved in research projects, such as clinical trials and cohort studies. These include funders, ethical committees, trial managers, researchers, practitioners and patient and public engagement leads. They may also be used by adolescents involved in participation activities to check that the provisions meet minimum ethical standards to ensure meaningful engagement.

The standards define specific and tailored requirements for four key accountable bodies:

- **Funders:** those responsible for the initiation, management, and/or financing of a research project.

⁷ World Health Organisation (2014) [Health for the World's Adolescents: A second chance in the second decade](#)

⁸ See Lansdown, G. (2005) [The Evolving Capacities of The Child](#) UNICEF Innocenti Research Cent

- **Research centre leadership:** those responsible for the governance, leadership and management of the research centre. This may include the sponsors of research projects and the Board of Directors/Trustees (including any non-executive directors) and the employed senior leadership team.
- **Research project leadership:** those responsible for the executive leadership of the research project. This is likely to include the Principal Investigator, Trial Managers and Coordinating Investigator (where they exist). As individuals, they may work across multiple research projects, but the standards apply to their role in a specific research project engaging adolescents.
- **Staff responsible for participation:** These are staff members with defined roles and responsibilities for the planning, delivery, and evaluation of participatory activities. This may be a standalone role (e.g. Patient and Public Involvement Officers/Coordinators) or it may be a task attached to a wider role. In some contexts, there may be multiple people with these responsibilities. They may be known by a variety of titles including Patient and Public Involvement Coordinators, Participation Officers, etc.

Some research centres or individual research projects may have specific participation structures, committees, leadership groups or dedicated staff. While tasks to meet these standards may be delegated to these specific roles, the standards have been set to those accountable for implementation.

Research Ethics Committees (also known as Independent Ethics Boards) can play a key role in championing adolescent participation. They review research project proposals and decide whether the approach to participation is ethical and by involving adolescents when designing their ethical approval processes and in individual decisions about research projects.

What do the standards cover?

The standards guide those involved in clinical research through the lifecycle of the research process - from research conception to concluding specific projects and reporting results. Thus they can be divided into the following topics:

- **Institutional and governance issues:** standards that form a foundation for meaningful and ethical participation. These relate to structural issues that must be considered for effective participation: strategy, staffing, policies and procedures, safeguarding, etc.
- **Setting a Research agenda:** standards related to how adolescents influence the scope and agreement of research topics and general lines of enquiry.
- **Plan and Design:** standards related to how adolescents influence the design and planning of research. These include decisions about the development of the research question and purpose of the study, the subject(s), location, partners/collaborators, the activities included in the project, the expected participation of adolescents (and others), the mechanisms and methods of their participation, and identification and mitigation of risks or other issues to be considered.
- **Delivery and management:** standards related to how adolescents influence the implementation of research projects. These consider decisions about how projects will be delivered in practice and how the project will be monitored and evaluated, including any participation activity.
- **Reporting of results:** standards related to how adolescents receive information about and how they influence the dissemination of the substantive results from research project(s).

What are the different levels of the standards?

Each standard has three levels of indicators of practice that can be met:

- **Primary:** this is the minimal level of practice required. These indicators show that the basic components of quality participation are met: adolescents receive sufficient information to make informed choices; they have opportunities to express themselves and their views are given due weight in decision-making. This level also includes basic requirements to ensure that participation practices and activities are safe and do not cause harm. Activities, institutions, or projects that do not meet the Primary level of practice are **unlikely** to be examples of meaningful or ethical participation.
- **Secondary:** these indicators of practice 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 indicators of practice seek to increase the autonomy and freedom of adolescents for self-initiated and self-directed activities within the context of the research centre or project. These focus on the engagement of adolescents with direct and specific experiences of diseases, illnesses, or conditions that influence decisions about research affecting them. These indicators ensure that adolescents themselves co-produce processes, lead decisions or develop materials that help them understand issues or express their views.

The practice demonstrated to meet indicators at the Primary level should be sustained unless superseded by an indicator at a subsequent level.

We recognise that participation is an ongoing process, not a one-off act. Over time, all organisations should consider transitioning to deeper and more meaningful practices. Research centres or projects may decide to progress the level of standards for different topics at a different pace dependent on their capacity, interest and what would make the most significant difference to how adolescents have influence.

How can the standards be used?

These standards gather expected practice for adolescent participation in clinical research. They can be used to:

- **Map current activity:** check the range of activities a project or centre is currently undertaking and the level of indicators of practice they relate to.
- **Plan for future progression:** consider any gaps in current provision or further develop the participation activity.
- **Provide inspiration for future activity:** examine standards that are not currently met or areas where the scale, breadth or quality of participation activities can be improved.

Each section includes standards and three levels of indicators of practice. We hope that the standards offer stimulation for reflection on current practice and that they will enable clinical researchers and users to apply and contextualise the indicators to each research type and setting. We have aimed to balance clarity in the description and expectation of adolescents' experience without being overly prescriptive that practice is stifled or constrained.

A note about Plans

The standards require the development of specific plans for adolescent participation. The aim is to ensure that there is a clear context-specific approach to how adolescents are involved and how they can influence decision-making. The process of developing a plan is often as important as the plan itself and the indicators expect that adolescents are engaged in decisions how they or other adolescents are involved.

Two specific plans are required with different focus areas:

- **Research Centres should have an 'organisational strategic plan for participation'.** This should describe how participation is embedded in the Centre's
- practices and should focus primarily on the overarching structures of direct involvement by adolescents in the Centre's decision-making. This includes issues such as general training for staff,

and processes for developing appropriate centre-wide policies and procedures.

- **Individual Research Projects should have a 'plan for participation in the research project'.** This should describe how participation will be implemented for a specific research project, with the relevant groups of adolescents in the specific context of the project.

We do not prescribe the exact format or content of a plan. You may decide to have a standalone plan for adolescent participation or use these standards within a wider plan on patient and public involvement including other groups of people. Alternatively, you may decide that it should be integrated within wider organisational or project planning processes. You will meet the standards by describing the overall approach, methods, responsibilities, budget and monitoring and evaluation processes for the participation of adolescents.

Plans may evolve, change and adapt during implementation. These should be living documents that guide relevant staff and those involved in any stage of the research projects to deliver meaningful, effective, and ethical participation.

Plans themselves do not impact the scale, breadth or quality of adolescent participation. However, we believe if they are developed through an inclusive and constructive process, they can positively shape participation activity. Plans bring clarity on what will happen by whom, when and codifies the commitment to participation. Transparency of a clear plan can assist young people and their allies to hold those with power accountable for implementation. It is only by acting on the plan that a positive difference can be made to adolescents' experiences. Judgements on effectiveness of participation or ethical practices should be primarily based on the experiences of adolescents not on the production or display of a plan.

2.

THE STANDARDS

Quality standards for adolescent
participation in clinical research
decision-making



A. Standards for funders

These standards are for those providing funding for a particular clinical research project or contributes to core costs of a clinical research centre.

Theme	Indicators		
	Primary	Secondary	Tertiary
1. Institutional and governance issues			
1.1 Funders consider the commitment of research project partners to adolescent participation.	<ul style="list-style-type: none"> Organisations must demonstrate their strategic and operational commitment for the participation of adolescents in research (e.g. in an institutional strategy or vision document or annual plan, etc) as a pre-requisite for funding, set by the funder(s). 	<ul style="list-style-type: none"> Funders undertake appropriate due diligence on an organisation's approach to participation of adolescents, including seeking evidence of relevant policies & procedures. 	
2. Setting a Research agenda			
2.1 Funders consider adolescents' views when setting research priorities.	<ul style="list-style-type: none"> Adolescents' views are considered when preparing the funding strategy and approach to funding 	<ul style="list-style-type: none"> Adolescents influence the design of the process for selecting research projects to receive funding. 	<ul style="list-style-type: none"> Adolescents with specific conditions co-create the funding strategy and approach to funding research for that condition or disease. Adolescents are part of the review process of applications for funding.

3. Plan and Design			
3.1 Funders actively ensure research centres and project leadership are competent to undertake ethical and meaningful participation.	<ul style="list-style-type: none"> Decision-making criteria for supporting a research project include adolescent participation in the design, delivery and dissemination. 	<ul style="list-style-type: none"> Funders require that any application for funding must state if and how adolescents have been actively involved in developing the research project plan and what has changed as a result of their participation. This should include overall research project management and site-specific information (including involvement in site selection). 	<ul style="list-style-type: none"> Funders ensures no project will be funded unless there is a credible and resourced plan for adolescent participation in research project design, delivery and evaluation. Funders undertakes a due diligence process to identify whether the Centre and the Project leadership are competent to deliver ethical and meaningful participation. Funders actively considers the growth in participation over time, encouraging a progressive sharing of power with adolescents in the Centre over time and across research projects or in specific multi-year research projects.
4. Delivery and management			
4.1 Funders actively monitor adolescent participation in supported projects	<ul style="list-style-type: none"> Funders request information on how adolescents are actively involved in the research project as part of regular reporting. This includes details on the number and diversity of the adolescents involved and details of what the outcome of the participation has been. 	<ul style="list-style-type: none"> Regular reporting includes details of how adolescents have been involved, what they have done, and whether their views have influenced change during the research project. 	<ul style="list-style-type: none"> Adolescents are involved in reviewing reports of participation activity received from funded research projects.

5. Reporting of results			
5.1 Funders actively monitor reporting of research results to adolescents	<ul style="list-style-type: none"> Funders request information on how results from a study were shared with adolescent participants. 	<ul style="list-style-type: none"> Funders set minimum standards regarding how results from a study are shared with adolescent participants. 	
5.2 Funders are accountable to adolescents		<ul style="list-style-type: none"> Funders produce information aggregating the research they have supported in a youth-friendly and accessible manner. 	<ul style="list-style-type: none"> Funders produce aggregate information for specific conditions on research they have funded and cumulative information in a youth-friendly and accessible manner. Adolescents influence or co-produce dissemination materials aimed at their peers.

B. Standards for research centre leadership

These standards are for those responsible for the governance, leadership and management of research centres. This may include the sponsors of research projects. This includes the Board of Directors/Trustees (including any non-executive directors) and the employed senior leadership team.

Theme	Indicators		
	Primary	Secondary	Tertiary
1. Institutional and governance issues			
1.1 The organisational strategy of the research centre includes a commitment to participation, which is actively monitored.	<ul style="list-style-type: none"> Participation activities are included in the organisation's strategy (i.e. there is a clear ambition to involve adolescents within decision-making and any specific structures or mechanisms for this). The organisation's strategy monitoring process explicitly includes tracking progress on participation (e.g. tracking activities, reviews of relevant plans, numbers engaged). 	<ul style="list-style-type: none"> The organisation's strategy explicitly reflects the commitments of Article 12 of the UN Convention on the Rights of the Child. Adolescents have shaped the organisation's strategy, including how they would like to be involved. Adolescents have access to youth-friendly information on the organisation's strategic commitment to participation (e.g. summary leaflets). Adolescents' views are sought and taken into account when assessing progress to meet the organisation's strategy. 	<ul style="list-style-type: none"> Adolescents have access to youth-friendly information on implementation of participation in the organisation. They should be informed about new participation activity and the progressive sharing of power with adolescents. The organisation develops specific structures for adolescents to be involved in monitoring the progress and quality of participation activity in the organisation (e.g. Young Inspectors, youth advisory boards, Youth Trial boards). Where relevant, the organisation's annual report includes details of the organisation's approach to participation. Details of adolescents' experiences of participation are made publicly available.
1.2 The research centre leadership actively support participation.	<ul style="list-style-type: none"> Organisational leaders are supportive and actively promote participation. They demonstrate this through statements to 	<ul style="list-style-type: none"> The organisation has a nominated Board level lead to champion adolescent participation in the organisation. 	<ul style="list-style-type: none"> Adolescents are involved in some form of participation mechanism to advise and shape the research centre strategy and delivery (e.g. Young People Advisory

	the team and their approach to managing and leading the centre.	<ul style="list-style-type: none"> Adolescents have a range of opportunities for safe, direct access to senior leaders in the organisation to share their own views and perspectives. 	<p>Group, Adolescent Treatment Group, Youth Trials Boards).</p> <ul style="list-style-type: none"> Adolescents are directly involved and represented within the research centre leadership structure (e.g. as members of the Board of Directors/Trustees).
1.3 The research centre has a strategic plan for participation and adopts a range of relevant policies and procedures.	<ul style="list-style-type: none"> An 'organisational strategic plan for participation' is developed and is influenced by the views of adolescents. A review of previous participation activity and resources that support participation inform the plan. A range of policies and procedures are developed to enable participation. This could be in the form of a specific policy and procedure or Standard Operating Procedure. It should include non-coercive compensation for adolescents involved. Reasonable resources (including funding, staff, time) are assigned for participation activities. This includes a specific budget for expenses related to adolescents' involvement. 	<ul style="list-style-type: none"> The 'organisational strategic plan for participation' includes timebound objectives for participation activity range, quality, and depth. The plan names key partners which will enable the organisation to progress participation. The 'organisational strategic plan for participation' is publicly available. Operational delivery plans (e.g. annual business plans) include details of participation activities and relate to the 'organisational strategic plan for participation'. 	<ul style="list-style-type: none"> The 'organisational strategic plan for participation' is reviewed at least every two years and influenced by the views of adolescents. The 'organisational strategic plan for participation' – or a summary of it – is published in a youth-friendly format. Where relevant, the organisation's annual report includes reporting on the progress of the 'organisational strategic plan for participation'.
1.4 The research centre has appropriate staffing and resourcing for meaningful and ethical participation.	<ul style="list-style-type: none"> The roles and responsibilities for those responsible for participation activities are identified and shared internally. 	<ul style="list-style-type: none"> The names and contact details of those responsible for participation are shared publicly (e.g. on website). Details of their role and responsibilities are made available. 	<ul style="list-style-type: none"> There are paid employment opportunities for adolescents (e.g. as trainers, researchers, mentors, supporters).

<p>1.5 The research centre staff are given appropriate training, supervision, and support to enable them to ensure meaningful and ethical participation.</p>	<ul style="list-style-type: none"> • Staff responsible for participation activities have access to learning and development opportunities relevant to their role. • Staff responsible for participation activities have line management and supervision by people who have a knowledge of working safely with adolescents. • Staff can express any views or anxieties about involving adolescents and expect these to be addressed in a constructive way. 	<ul style="list-style-type: none"> • All staff are informed of the organisation's commitment to participation (e.g. through awareness-raising and through their induction). • All staff have the opportunity to shape the organisation's approach to participation, sharing views and experiences. These are given due weight in decision-making. • Staff responsible for participation activities have access to tools and other development opportunities (including links with peers in other organisations). Key skills developed are likely to include facilitation and participation methodologies and identifying, including, and supporting at-risk groups. • Staff responsible for participation take part in an annual appraisal, which includes progress on participation. 	<ul style="list-style-type: none"> • Staff involved in research projects with adolescents have access to relevant learning and development opportunities in adolescent participation. • All staff involved in research projects with adolescents have opportunities for safe, facilitated 'interaction activities' with adolescents. These activities provide the opportunity for adolescents to share their learning from the participation activities they have been involved in. • Staff responsible for participation activities have access to a mentor and are able to support other organisations to develop their participation activity. • Staff responsible for participation activities have access to additional advanced training relevant to participation (e.g. writing information to share with adolescents, specific participation methods, working online, engaging specific groups). • Staff responsible for participation activity engage with mentors/supervisors with expertise in participation and are given space for critical reflection. • The views of adolescents are sought and influence the annual appraisal of staff who have held direct relationships with them (e.g. staff responsible for participation). • External stakeholders are consulted and involved in shaping the organisation's approach to participation.
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<p>1.6 The research centre has arrangements in place for complaints from adolescents involved in participation activities.</p>	<ul style="list-style-type: none"> Complaints about the process of participation are dealt with fairly and without victimisation. 	<ul style="list-style-type: none"> The organisation has a Complaints Policy, which includes details of how complaints are received and resolved, ensuring adolescents to make a complaint in confidence about any issues concerning their involvement. Any adolescents involved in participation activities are provided with youth-friendly and accessible information on their right to complain. 	<ul style="list-style-type: none"> The organisation includes information on complaints related to participation activity in its annual report (where relevant) and on its website.
<p>1.7 The research centre has arrangements to ensure the safeguarding of adolescents involved in participation activities.</p>	<ul style="list-style-type: none"> The organisation has a Safeguarding Policy which details how it meets the organisation's duty of care to those involved in participation activity. For each participation activity, a member of staff is nominated to take responsibility for the safety, welfare and safeguarding of participants. They will take a lead for the wellbeing and support needs of the adolescents. All staff with duties to care and supervise adolescents are provided with information and training to work safely and effectively with adolescents. This should include familiarisation with safeguarding responsibilities and the procedures to be followed if anyone has any concerns about an individual's safety or welfare. All staff with duties to care and supervise adolescents have completed a background check to ensure their suitability to work with adolescents, including - where available - any criminal record. The check must meet the highest standard available in the jurisdiction. Any adolescents involved in participation activities are provided with youth-friendly 		<ul style="list-style-type: none"> The organisation includes information on safeguarding in participation activity in its annual report (where relevant) and on its website.

	<p>and accessible information on their right to be safe and how to raise concerns that they have experienced or are at risk of harm.</p> <ul style="list-style-type: none"> • Appropriate insurance should cover any loss or injury experienced by adolescents engaged in participation activities. 		
2. Setting a Research agenda			
2.1 The priorities of the research centre for future research projects is informed by the views of adolescents.	<ul style="list-style-type: none"> • The research centre will consider the known views of adolescents when agreeing on the research agenda for the Centre. This may be through a desk-based review of previous participation activities. Gaps in what is known about the views and experiences of adolescents are identified. 	<ul style="list-style-type: none"> • Adolescents with specific conditions co-create the research strategy and approach for that condition or disease. • Where appropriate, the organisation seeks to fill the gaps in what is known about the views and experiences of adolescents when making decisions on future research priorities. • A statement is written which explains how the views and experience of adolescents with specific conditions have influenced or not, and why this research topic has been selected. 	<ul style="list-style-type: none"> • Adolescents are engaged in the design and agreement of research strategy. Their views are considered and taken seriously in any decisions about the Centre's research agenda.
3. Delivery and management			
3.1 The research centre has systems for monitoring and learning from its participation activities.	<ul style="list-style-type: none"> • Recording systems are developed to track the nature of participation activities across the organisation and the numbers of people involved, including basic aggregated demographic data on those involved across projects. 	<ul style="list-style-type: none"> • There are public statements of learning and achievements from participation activities (e.g. blogs, statements in annual reports, reports, videos). • Summary data on who is involved in participation activity is made publicly available (e.g. Basic aggregated demographic data). • There is an organisation-wide process in place to regularly monitor, review, and report on participation. This brings together those with responsibilities across different research projects at the 	<ul style="list-style-type: none"> • Where relevant, the organisation's annual report includes statements of learning and achievements from adolescent participation activities, including the direct views of adolescents of each activity. This includes a statement of changes, benefits and learning resulting from participation activity. • Learning from participation activities is shared with likeminded organisations (e.g. through participation in relevant networks).

		research centre to share learning and good practice.	<ul style="list-style-type: none"> Where relevant, we advocate for greater participation of adolescents in decision-making in clinical research.
4. Reporting of results			
4.1 Staff are supported to produce youth-friendly dissemination materials.	<ul style="list-style-type: none"> Staff who produce dissemination materials have access to training and support to produce easy-to-read, youth-friendly and accessible materials. 	<ul style="list-style-type: none"> There is access to specialist resources (graphic designers, web developers) to advise and support the development of dissemination materials. 	<ul style="list-style-type: none"> Adolescents influence or coproduce dissemination materials aimed at their peers.

C. Standards for research project leadership



These standards are for those responsible for the executive leadership of a specific research project. This is likely to include the Principal Investigator, Trial Manager and Coordinating Investigator (where they exist). As individuals, they may work across multiple research projects, but these standards apply to their role in one specific research project with adolescents.

Theme	Indicators		
	Primary	Secondary	Tertiary
1. Setting a Research agenda			
1. 1 Adolescents' views are considered when the specific research topic and question for the project are developed.	<ul style="list-style-type: none"> Research on any published views and the experiences of adolescents relevant to the area of investigation is conducted. The known views are given due weight when considering research priorities. Gaps in what is known about the views and experiences of adolescents are identified. 	<ul style="list-style-type: none"> Research on the published views and experiences of adolescents with the specific health conditions is conducted and given due weight when considering research priorities. 	<ul style="list-style-type: none"> Adolescents with specific health conditions co-create the research questions and approach for a specific project.
2. Plan and Design			
2.1 The research project sets a clear plan for participation.	<ul style="list-style-type: none"> Adequate time is included in the project design for meaningful participation of adolescents from its conception to conclusion. Review any key informants, patient representative groups and youth-led organisations which are relevant to the study. They are made aware of the study and invited to engage at key points. A 'plan for participation in the research project' is developed and is influenced by the views of adolescents. The plan includes a clear statement on the purpose of participation for the study. This includes where participation is to be 	<ul style="list-style-type: none"> Adolescents are involved from the earliest possible stage and co-design participation for the rest of the research project. Contact is made with relevant patient representative groups and youth-led organisations that are relevant to the study. They are given the opportunity to influence the research design and the 'plan for participation in the research project'. A 'plan for participation in the research project' is co-developed with adolescents. 	<ul style="list-style-type: none"> Adolescents are involved in the development of applications for new research projects. The plan sets clear targets for the involvement of marginalised and socially excluded groups. The plan explains includes supporting the transition of those no longer eligible for participation activities (e.g. aging out). For multi-site research projects, adolescents involved in participation activities or 'participation mechanism' have opportunity to interact (in person or virtually).

	<p>maximised and areas where participation activity is less likely and clarity on who will make final decisions as to where participation activities will or will not take place.</p> <ul style="list-style-type: none"> The plan states a named person responsible for the specified participation activity. The roles and responsibilities of those responsible for each participation activity is stated. The plan states how the selection process for participatory activities will be inclusive, fair, and transparent. The plan includes a clear timeline for distinct phases of participation activities. For multi-site research projects, the plan states the different mechanisms of participation for each site, given its role in the project, capacity and capability. When drafting the study budget, resources (including staff time, activity costs, compensation, adolescents' expenses) are allocated for participation activity that reflect the actual costs of adolescent participation. 	<ul style="list-style-type: none"> The plan states how groups with the biggest barriers to participation will be reached and engaged. The plan includes the information or training that will be provided to adolescents to ensure their equal access to participation (e.g. the medical topics that need to be defined). For multi-country or site studies, adolescents from each country or site are represented in the 'participation mechanism'. There is a specific budget available for expenses related to adolescents' involvement. There is a clear communications plan for participation with a range of inclusive methods used to reach different audiences. Adolescents are involved in some form of 'participation mechanism' to steer, advise and shape the research project (Young People Advisory Group, Adolescent Treatment Group, Youth Trials Boards etc). The views of the 'participation mechanism' are fed into any research project steering committee or group (for example, the Trial Steering Committee). As a minimum requirement, a named adult advocate represents their views. 	<ul style="list-style-type: none"> Adolescents are represented directly in any project steering committee or group (for example, the Trial Steering Committee). Adolescents have direct control over an identified budget for them to pursue their own participation activity which meets the overall goal of involvement in the project. Partnerships are made with relevant youth-led organisations to support wider representation of young people.
2.2 The research protocol is informed by adolescents.	<ul style="list-style-type: none"> Where relevant, adolescents involved in participation activities have access to the research protocol. 	<ul style="list-style-type: none"> Where relevant, adolescents involved in participation activities are provided with youth-friendly information about the Research Protocol. Where relevant, the Research Protocol is developed and influenced by the views of 	

		adolescents. This should include any specific consideration of gaining consent from study participants.	
2.3 The research project approach to managing risk is informed by adolescents.	<ul style="list-style-type: none"> Where relevant, adolescents involved in participation activities have access to information on how risk is being managed. 	<ul style="list-style-type: none"> Where relevant, adolescents involved in participation activities are provided with youth-friendly information about how risk is managed. Where relevant, the research project's approach to identifying and responding to research project-related harms should be developed and influenced by the views of adolescents. This should include physical harm, as well as social harms. 	
2.4 The research project informs adolescents of their right to be involved and supports them to actively participate.	<ul style="list-style-type: none"> Adolescents participating in the research study are provided with youth-friendly information of how they or other adolescents can be involved in participation activities. They have access to easy-to-follow instructions for access/using remote/online platforms. 		
3. Delivery and management			
3.1 The Research Project monitors and learns from its participation activity.	<ul style="list-style-type: none"> The plan for participation is regularly (and at least annually) monitored, reviewed, and updated. The revised plan is influenced by the views of adolescents. The research team annually appraise how they have considered adolescents' views and implemented this into the research process or outcome. 	<ul style="list-style-type: none"> Staff share with other stakeholders about the ways adolescents have influenced the research design, delivery, and/or influenced the substantive research findings. 	
4. Reporting of results			
4.1 Adolescents are informed of the results of the study and its approach to participation in a youth-friendly manner.	<ul style="list-style-type: none"> Adolescents who took part in the study receive dissemination materials, which accurately detail results from the study in a easy-to-read, youth-friendly and accessible manner. The needs of different 	<ul style="list-style-type: none"> Adolescents influence the development of dissemination materials for study participants. Adolescents influence the development of dissemination materials for a range of audiences. 	<ul style="list-style-type: none"> Adolescents participants of the study co-create or develop their own dissemination materials in order to share the results from the study aimed at other study participants.

	adolescents are met through inclusive and flexible communication methods.		<ul style="list-style-type: none"> Adolescents who took part in the study help to promote dissemination materials for a range of audiences. Adolescents who took part in the study are invited to offer feedback and comment on the results of the study. Their views are captured and considered in shaping future research.
4.2 Adolescents are recognised in any relevant research result publication	<ul style="list-style-type: none"> Where relevant and with consent of the adolescents, any participation mechanism which has shaped the project is acknowledge in research outputs (e.g. journals, chapters, etc). 	<ul style="list-style-type: none"> Staff always consider whether adolescents have made a substantial contribution to the research results and whether this means they should be listed as co-authors. Where relevant, with consent of the adolescents and mindful of any confidentiality due to the nature of any health condition, individuals (or a shortened version/pseudonym) are named in research outputs (e.g. journals, chapters, etc). 	

D. Standards for staff responsible for participation

These standards apply to the staff with defined roles and responsibilities for the planning, delivery and evaluation of participation activities with adolescents. As individuals, they may work across multiple research projects, but these standards apply to their role in one specific research project with adolescents.

Theme	Indicators		
	Primary	Secondary	Tertiary
1. Institutional and governance issues			
1.1 All staff working on the research project understand participation.	<ul style="list-style-type: none"> Staff demonstrate an understanding of participation throughout the research process. 	<ul style="list-style-type: none"> Staff have attended participation training. 	
1.2 The research centre has appropriate staffing to ensure meaningful and ethical participation.	<ul style="list-style-type: none"> Staff responsible for participation activity are willing and have chosen to undertake these activities. 	<ul style="list-style-type: none"> Staff responsible for participation activity are recruited for the role based on their demonstrable skills, knowledge, and experience. 	<ul style="list-style-type: none"> Adolescents are involved in the recruitment and selection of staff responsible for participation activity (e.g. they are involved in designing role descriptions, shortlisting applicants or sit on interview panels or assessment processes). Adolescents involved in the assessment of staff performance of staff responsible for participation activity (e.g. their views influence annual appraisal processes). There are paid employment opportunities for adolescents (e.g. as trainers, researchers, mentors, supporters).

2. Plan and Design			
2.1 The research project informs adolescents of their right to be involved.	<ul style="list-style-type: none"> Staff will have designed and produced youth-friendly publicity and recruitment material such as leaflets, posters and presentations for participation activities. 	<ul style="list-style-type: none"> Adolescents involved in any participation activity are given youth-friendly information about the research project. This should include information on the full range of potential outcomes from the project and the timeline for the project. 	<ul style="list-style-type: none"> Adolescents are involved in the production of youth-friendly publicity and recruitment material for participation activities.
3. Delivery and management			
3.1 The Research Project staff are clear on their role in participation activities and confident in their roles and responsibilities.	<ul style="list-style-type: none"> During any participation activity, other staff supporting the activity are given clear and detailed briefings on their roles and responsibilities. They must have all relevant safeguarding checks in line with local legislation. Staff have a basic understanding of participation work with adolescents, including the nine key principles of ethical and meaningful involvement (see Appendix C). 	<ul style="list-style-type: none"> During any participation activity, other staff supporting the activity receive training on adolescent participation practices. 	
3.2 Adolescents involved in any participation activity are treated with dignity and respect.	<ul style="list-style-type: none"> Staff are friendly, welcoming and engage in informal conversation as appropriate. Staff create a welcoming and accessible environment for adolescents. Everyone is made aware of expectations of the way they should behave in this environment (e.g. Codes of Conduct or Ways of Working). Staff are never possessive or territorial and actively support adolescents to engage in other participation activities. 	<ul style="list-style-type: none"> Adolescents involved in participation activities influence any expectations of behaviour on anyone engaged (e.g. Codes of Conduct or Ways of Working). 	<ul style="list-style-type: none"> Staff working with adolescents educate themselves and others about the causes and effects of social exclusion amongst young people, to understand certain behaviours. Staff apply anti-oppressive practices taking positive steps to address oppressive language, attitudes, practices and structures, and challenging negative discrimination.
3.3 Adolescents give their consent to be involved in participation activities.	<ul style="list-style-type: none"> Adolescents' choice whether to take part in any activity is always respected. There is no coercion, pressure or obligation on an individual to participate or offer a view. There is no link between views expressed 		

D. Standards for staff responsible for participation

	<p>and refunding of expenses or the provision of incentives or honorarium.</p> <ul style="list-style-type: none"> Adolescents give their personal informed consent for their involvement in any participation activity. This is in addition to any legal requirements for parental or legal guardian consent. 		
3.4 Adolescents who take part in participation activities are communicated with appropriately.	<ul style="list-style-type: none"> Staff working with adolescents adopt appropriate styles of communication (e.g. no jargon, no complicated or patronising language). Staff working with adolescents ensure that non-verbal communication is appropriate and safe (e.g. friendly tone, open body language, respectful of physical boundaries). Staff working with adolescents adopt appropriate methods of communication, including electronic channels (e.g. communicating on platforms the adolescents use). Staff working with adolescents understand requirements regarding confidentiality and the importance of meeting these. 	<ul style="list-style-type: none"> Adolescents involved in participation activities are informed about any boundaries to confidentiality, especially if they share information that might require further action, such as their involvement in illegal activities or issues of harm. 	<ul style="list-style-type: none"> Staff working with adolescents use translators, interpreters or communication aids where necessary to aid inclusion.
3.5 Adolescents who take part in participation activity are provided with appropriate support.	<ul style="list-style-type: none"> Staff provide appropriate refreshments to adolescents participating in events (e.g. drinks, snacks or meals). Staff ensure that all costs related to an adolescents' participation are paid for or reimbursed such as data and phone credit and relevant travel costs (which may include costs of visas, insurance, vaccines, etc). Staff take all efforts to provide immediate reimbursements to adolescents – or, where appropriate, their parents/carers (e.g. immediate reimbursement for public 	<ul style="list-style-type: none"> Adolescents who are experiencing issues or challenges related to the research project are offered practical or emotional support. Staff have systems for adolescents to avoid incurring any up-front costs related to participation (e.g. staff buy travel in advance). Staff inform adolescents, and, where appropriate, their parents/carers of any legal, tax or social security implications for repayment of expenses or provision of any honorarium. 	<ul style="list-style-type: none"> Adolescents who are experiencing issues or challenges unrelated to the research project are offered appropriate immediate practical support and signposting to other appropriate services, including health or medical care where necessary. Adolescents involved in participation activities are informed about other participation opportunities and resources for their personal and professional development.

D. Standards for staff responsible for participation

	transport costs to attend an event). Where this is not possible, staff ensure that adolescents' expenses are repaid promptly.	<ul style="list-style-type: none"> Where an adolescent is travelling to a different country, they are provided with youth-friendly information about the place prior to travel (e.g. details on travel, safety, language, money, etc). 	<ul style="list-style-type: none"> Adolescents who no longer become eligible for participation activities (e.g. they become too old) are offered support and signposted to alternative activities.
3.6 The research project approach to participation is inclusive using appropriate methods.	<ul style="list-style-type: none"> Where methods of participation will include some selection of adolescents, these will be fair, inclusive, and transparent with steps to ensure no discrimination due to age, sex, gender identity, disability, sexual orientation, or any other reason. Methods and facilitation techniques do not discriminate against adolescents, are accessible and promote equal access. Over the course of the research project and individual participation activities, a range of methodologies and approaches are used to engage adolescents. 	<ul style="list-style-type: none"> Creative methodologies – such as the use of art, play-based, re-enactments and/or simulations - are used to engage adolescents. 	<ul style="list-style-type: none"> Adolescents help to decide what methods are used.
3.7 The research project builds adolescents' knowledge and skills to enable them to actively participate in any relevant participation activity.	<ul style="list-style-type: none"> Participation activities are only delivered where adolescents have the relevant knowledge or skills to participate or given opportunity to develop them. 	<ul style="list-style-type: none"> Adolescents involved in any participation activity are given relevant training to develop their skills to express themselves and be heard. 	<ul style="list-style-type: none"> Adolescents co-facilitate training other adolescents involved in any participation activity. Adolescents play a peer support role to other new members involved in any participation mechanism.
3.8 The Research Project seeks, collects and reviews the views of adolescents involved in participation activities.	<ul style="list-style-type: none"> Adolescents involved in any participation activity receive feedback in a youth-friendly manner on what's changed due to their engagement. Adolescents involved in any participation activity are regularly and anonymously asked for feedback about their satisfaction with the participation process and how it could be improved. Staff review and reflect upon the feedback of adolescents who have been involved in any participation activity and make 	<ul style="list-style-type: none"> Adolescents who take part in the research project receive information in an age accessible manner about other adolescents' involvement in the research, how their views have been interpreted/used, and what has changed as a result. Adolescents involved in any participation activity receive information on the results of any monitoring and evaluation of the participation activity and how staff intend to respond to or take action in response 	<ul style="list-style-type: none"> Adolescents are actively involved in collection and analysis of feedback from peers on their satisfaction with the participation process and how it could be improved. Staff publicly publish the ways adolescents have influenced the research design, delivery and/or influenced the substantive research findings. This could be via a blog on their website, or a project newsletter.

D. Standards for staff responsible for participation

	decisions about what they will change as a result.	<p>to this feedback. This is communicated in an age accessible manner, and they are given opportunities to feedback on the results.</p> <ul style="list-style-type: none"> • Staff share with other stakeholders how adolescents have influenced the research design, delivery and/or influenced the substantive research findings. • Where there is a multi-year research project, different young people are recruited to participate in the activity through the course of the project to ensure the current experiences of being an adolescent are being represented. 	
3.9 The research project staff acknowledge adolescents involved in participation activities.	<ul style="list-style-type: none"> • Staff will act as a referee for adolescents involved in participation activities (e.g. being a reference for education or work or writing a letter of support). 	<ul style="list-style-type: none"> • Adolescents involved in participation activities receive some form of certification in recognition of their involvement. 	<ul style="list-style-type: none"> • Adolescents involved in participation activities receive some form of incentive, honorarium, or gift in recognition of the time and energy spent on participation in the project.

3.

APPENDICES

Guidance for Research
Ethics Committees
Key Terms
Basic requirements for
participation



Appendix A: Research Ethics Committees' roles in supporting adolescent participation

Research Ethics Committees (also known as Independent Ethics Boards) play a key role in protecting the rights, safety, and well-being of people involved in and affected by clinical research. They ensure that research centres and those working on research projects embed an ethical approach into all aspects of their work.

The development process for these Standards did not actively engage enough representation from this area to allow for a set of Standards specific to Ethics

Committees, but it is acknowledged that this would be the next development of this work.

As a general rule, clinical research projects do not need to apply for ethical approval from RECs to involve the public in the planning or the design stages of research.⁹ Research Ethics Committees (RECs) can play two key roles in increasing the breadth, scale and quality of adolescent participation.

Scrutinising adolescent participation

Research ethics committees could play a role by:

- Designing their ethical approval process to include an assessment of potential ethical issues that could arise from the planned participation (or lack thereof) of adolescents in clinical research project design, delivery and evaluation.
- Asking for proposals for ethical approval to indicate how adolescents have been involved in shaping research project design and/or the proposed project ethical decisions (e.g. submission to RECs include details on adolescent participation).
- Actively considering the ethical issues arising from participation activities within clinical research projects. As a minimum requirement, this would be done when adolescents involved in participation activities have direct contact with research participants. More broadly, RECs could, for example:
 - ensure that the process for adolescents who are involved in any planned consultation or decision-making process is truly voluntary and based upon freely given informed consent for participation;
 - scrutinise permission required for adolescents to be involved in any participation process to ensure that researchers respect the adolescents' evolving capacity for autonomous decision-making;
 - scrutinise safeguarding procedures and personnel checks to ensure that risks of harm to adolescents consulted or involved in decision-making are minimised;
 - check that dissemination plans of the results of any research includes informing research participants in a manner that is age-appropriate.
- Actively considering how they direct research projects to meet ethical issues when their work has been informed by the views of adolescents. RECs play a key role in protecting research participants and should ensure that they meet their duties. When considering amendments to research projects, RECs should be mindful of how the project has been informed by the views of adolescents and whether directions that override the views adolescents have expressed through a quality participation process is proportionate to the risk of harm or poor practice identified.

Involving adolescents in REC decision-making process

Research ethics committees could play a role by:

⁹ C.f Health Research Authority / INVOLVE (2016) [Public involvement in research and research ethics committee review](#).

- Ensuring that their ethical review process has been informed by the views of adolescents. They may consult or actively involve adolescents regarding the standards of evidence research projects should demonstrate to ensure they are ethical.
- Consulting or actively involving adolescents in reviewing the applications for ethical approval regarding research into adolescent health. The views of adolescents should be considered and given due weight before decisions on ethical approval are made by the REC. Examples of activities could include:
 - Considering adolescents themselves understand draft patient information sheets for a specific project
- Consulting or actively involving adolescents in reviewing updates and annual reports or amendments to research ethics plans.

Appendix B:

Key terms

Note, some of these terms stem from Good Research Practice.¹⁰

Adolescent	The World Health Organization (WHO) defines adolescents as those people between 10 and 19 years of age. ¹¹
Adolescent involved in participation	This is an individual who is engaged through a participation activity. They may be involved through a specific participation mechanism or take part in a participation methodology. Distinct from a 'Research participant' who may be taking part in the clinical research project but not influence the design, delivery or evaluation of the project.
Children	Defined in the UN Convention on the Rights of the Child as a person under the age of 18 years.
Funder	Good Research Practice defines them as: The organisation that provides money for a particular clinical research project or contributes to core costs of a clinical research centre.
Independent Ethics Boards/Research Ethics Committees	Good Research Practice defines them as: An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Interaction activities	Opportunities for research project staff and leaders to meet directly with adolescents. These semi-structured sessions or activities provide an opportunity for all staff – including those in roles which do not traditionally have contact with adolescents – to directly hear and understand young people's perspectives.
Investigator	Good Research Practice defines this as: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Participation	There is no universal definition of participation and it is sometimes called engagement or involvement. Broadly, it is about ensuring that research is carried out 'with' or 'by' patients and/or members of the public rather than 'to', 'about' or 'for' them. We define participation as the process by which individuals and groups can influence decision making and bring about change. ¹² The focus is both that views are heard and that they are given due weight in decision-making.
Participation mechanism	The specific structure which allows adolescents to meet, discuss, debate and express views. This could include forums, councils, panels, or boards. They may be a self-selecting group, a group selected by adults, or an open group with variable membership or an elected/representative body.
Participation methodologies	The specific activities or tools used to support adolescents to form, consider and express their views, wishes and feelings.
Protocol	Good Research Practice defines this as: A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

¹⁰ International Council For Harmonisation Of Technical Requirements For Pharmaceuticals For Human Use (2016) [Integrated addendum to ICH E6\(R1\): Guideline For Good Clinical Practice](#)

¹¹ World Health Organisation (2014) [Health for the World's Adolescents: A second chance in the second decade](#)

¹² Adapted from Treseder, P. (1997) Empowering Children and Young People: Promoting Involvement in Decision-Making Save the Children.

Research Centre Leadership	Those responsible for the governance, leadership and management of the research centre. The structure of leadership may vary significantly depending on the legal status, size, and form of the institution which undertakes multiple research projects. This is likely to include the Board of Directors/Trustees (including any non-executive directors) and the employed senior leadership team.
Research participant	An individual who participates in a clinical research project. This could be as a recipient of the investigational product(s) or as a control. Sometimes called a subject. Distinct from an 'Adolescent involved in participation'.
Research Project	Any clinical trial or study, meta-analysis and epidemiological studies with human subjects. Good Research Practice defines a clinical trial as: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
Research Project Leadership	The executive leadership of the research project. This is likely to include the Principal Investigator, Trial Manager and Coordinating Investigator (where they exist).
Safeguarding	Actions taken to promote the welfare of children, young people and adults at risk of harm (may also be known as vulnerable adults) and to protect them from harm.
Sponsor	Good Research Practice defines this as: An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Staff	The team of people involved in the implementation and conduct of the clinical research project. This may include the Principal Investigator, Co-investigator, Research Associates, Data Managers, Study managers or coordinators.
Staff responsible for participation activities	These are the staff with defined roles and responsibilities for the planning, delivery and evaluation of participation activities. This maybe a standalone role (e.g. Patient and Public Involvement Officers/Co-ordinators) or it may be a task of a wider role. In some contexts, there maybe multiple people with these responsibilities. They may be known by a variety of titles including patient and public involvement coordinators, participation officers.
Youth-friendly	A version that is written and designed to be understood by all young people and summarises the key points of the original document. Prof. Laura Lundy describes these documents as 'needing to be age appropriate, accurate, accessible and appealing'. ¹³
Young people	There is no universally agreed international definition of youth or young people. For statistical purposes, the United Nations defines 'youth' as those persons between the ages of 15 and 24 years. ¹⁴

¹³ Lundy, L. (2012) [Creating child-friendly versions of written documents: a guide](#) European Commission

¹⁴ United Nations General Assembly (1981) [General Assembly Resolution 36/28, International Youth Year: Participation, Development, Peace](#)

Appendix C: Basic requirements for ethical and meaningful participation

The UN Committee on the Rights of the Child, which monitors the implementation of children's rights, has issued a General Comment on The Right of the Child to be Heard. This provides its comprehensive interpretation of the provisions of UN Convention on the Rights of the Child and how they understand children's right to be heard.¹⁵

This states that in all processes in which a child or children are heard and participate, must be:

- **Transparent and informative** – children must be provided with full, accessible, diversity-sensitive and age-appropriate information about their right to express their views freely and their views to be given due weight, and how this participation will take place, its scope, purpose and potential impact;
- **Voluntary** – children should never be coerced into expressing views against their wishes and should be informed that they can cease involvement at any stage;
- **Respectful** – children's views have to be treated with respect and they should be provided with opportunities to initiate ideas and activities. Adults working with children should acknowledge, respect, and build on good examples of children's participation, for instance, in their contributions to family, school, culture and work environments. They also need an understanding of the socio-economic, environmental and cultural context of children's lives. Persons and organizations working for and with children should also respect children's views with regard to participation in public events;
- **Relevant** – the issues on which children have the right to express their views must be of real relevance to their lives and enable them to draw on their knowledge, skills and abilities. In addition, space needs to be created to enable children to highlight and address the issues they themselves identify as relevant and important;
- **Child-friendly** – environments and working methods should be adapted to children's capacities. Adequate time and resources should be made available to ensure that children are adequately prepared and have the confidence and opportunity to contribute their views. The fact that children will need differing levels of support and forms of involvement according to their age and evolving capacities must be considered and taken into account;
- **Inclusive** – participation must be inclusive, avoid existing patterns of discrimination, and encourage opportunities for marginalized children, including both girls and boys, to be involved. Children are not a homogenous group and participation needs to provide for equality of opportunity for all, without discrimination on any grounds. Programmes also need to ensure that they are culturally sensitive to children from all communities;
- **Supported by training** – adults need preparation, skills and support to facilitate children's participation effectively; to provide them, for example, with skills in listening, working jointly with children and engaging children effectively in accordance with their evolving capacities. Children themselves can be involved as trainers and facilitators on how to promote effective participation; they require capacity-building to strengthen their skills in, for example, effective participation awareness of their rights, and training in organizing meetings, raising funds, dealing with the media, public speaking and advocacy;
- **Safe and sensitive to risk** – in certain situations, expression of views may involve risks. Adults have a responsibility towards the children with whom they work and must take every precaution to minimize the risk of violence, exploitation or any other negative consequences of their participation. Actions necessary for appropriate protection will include the development of a clear child protection strategy, which recognizes the particular risks faced by some groups of children, and the extra barriers they face in obtaining help. Children must be aware of their right to be protected from harm and know where to go for help if needed. Investment in working with families and communities is important in order to build understanding of the

¹⁵ UN Committee on the Rights of the Child (2009) [General Comment No 12 The right of the child to be heard](#)
See also: Save the Children International (2021) [The Nine Basic Requirements For Meaningful and Ethical Children's Participation](#)

value and implications of participation, and to minimize the risks to which children may otherwise be exposed;

- **Accountability** – a commitment to follow-up and evaluation is essential. For example, in any research or consultative process, children must be informed as to how their views have been interpreted and used and, where necessary, provided with the opportunity to challenge and influence the analysis of the findings. Children are also entitled to provision of clear feedback on how their participation has influenced any outcomes. Wherever appropriate, children should be given the opportunity to participate in follow-up processes or activities. Monitoring and evaluation of children's participation needs to be undertaken, where possible, with children themselves.



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