Advancing International Pediatric Clinical Research

PART TWO

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

February 2, 2022

8:00PM – 10:00PM EDT

This series is supported by an FDA Scientific Conference Grant.

MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

The MRCT Center

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Promoting Global Clinical Research in Children

Where we started & why this is important:

- Children **deserve access** to safe and effective medicines
- Children **historically excluded** from or underrepresented in research
- **Pediatric population widely dispersed** so clinical trials must be conducted in multiple jurisdictions
- **Persistent ethical issues:** while governing ethical principles may be generally agreed upon, differences in interpretation and application of principles exist
- Differing or nonexistent pediatric **regulations**
- Challenges in **trial initiation and conduct**
- The **pediatric patient and family voice** is not routinely solicited nor included in research life-cycle**.**
- **Children are not routinely offered a seat at the table.**

Project objectives

Broadly, sought to identify and propose solutions to regulatory, ethical, and operational challenges

- Current global landscape of pediatric research governance, focusing on legislative, regulatory, and guidance gaps and inconsistencies
- Identify current initiatives to improve pediatric research globally
- Identify challenges related to decision making by and on behalf of children
- Address benefit and risk considerations that create barriers and inefficiencies in transnational research with children.
- Identify meaningful ways to engage patients/families/community members

- Diverse leadership (Academia, EMA, Industry, participant advocates)
- 80+ members from all stakeholder groups with geographic diversity

Webinar Series: *Advancing International Pediatric Clinical Research*

- Funded through an FDA scientific conference grant award
- 5 virtual webinars; each session planned to be hosted twice, with similar content and different speakers and panelists, to allow for wide attendance and participation.
- An offshoot of the MRCT Center's *Promoting Global Clinical Research in Children* project

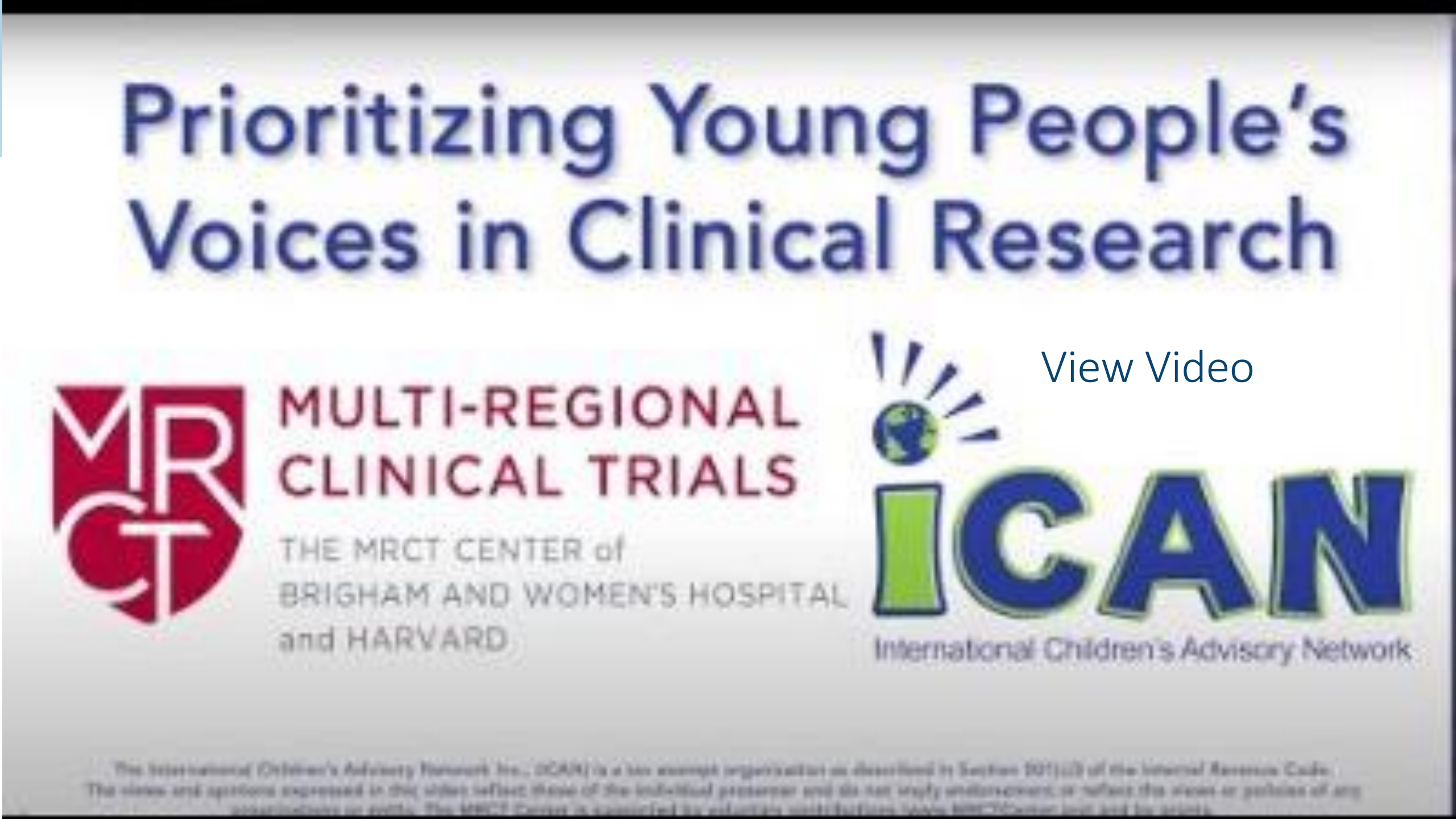
Advancing international pediatric clinical research—looking ahead

1. *Informing the future from COVID-19 lessons learned:*
   6 October 2021 & 7 October 2021
2. 2 February 2022: *Time to Listen—Hearing from young people in clinical research*
3. June 2022 : Decision making at ethics committee level including strengthening of ICH E11, concept of an ethical floor
4. Fall 2022: Regulatory convergence to facilitate international cooperation
5. Early 2023: TBD

Today:

Please see ”Bio Book” for extended introductions to the speakers and panelists

Prioritizing Young People's Voices in Clinical Research



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KEYNOTE SPEAKER

Dr. Sandhya Kanaka Yatirajula
The George Institute for
Global Health, India

YOUTH GUEST SPEAKER

Rohit

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Adolescent ‘Experts’ take the lead – Experiences and Lessons from ARTEMIS

Dr. Y.K.Sandhya
George Institute for Global Health

The George Institute for Global Health

Better treatments
Better care
Healthier societies

UKRI Medical Research Council

Research and engaging with adolescents and children

- Prior to 1988, much of the research on children and young people was adult centric (Coyne I. 1988)
- Data about children and young people was collected by consulting their parents/guardians/adults close to them
- The child was treated as a passive participant
- Such type of research failed to take into consideration the child's ability to contribute

Recognising children as ‘social actors’

- The passing of the UN Convention on the Rights of the Child in 1988 marked a significant change in the way children were perceived

- Researchers began to realise that it was necessary to talk to the children themselves about their experiences and feelings

- The World Medical Association in 1989 recognised that it was necessary for researchers working with children/young people, to not only seek consent from their parents but also to seek consent from the children/young people themselves

- Children began to be recognised as ‘social actors’ who possessed ‘genuine competencies’ that were as valid as that of adults

Engaging with adolescents in ARTEMIS

- ARTEMIS (Adolescent Resilience and Treatment Needs for Mental Health in Indian Slums) – A cluster randomised controlled trial running in two cities in India)

- Covering approximately 70,000 adolescents

- **Aim** - To test whether a community-based anti-stigma campaign leads to significant improvements in community behaviours toward adolescents with stress, depression and increased risk of self-harm/suicide

- ARTEMIS has very consciously incorporated the ethical aspect of working with adolescents.

- The setting up of the AEAG is a step in the direction of ethical research that views adolescents as active participants who are the most competent to design and deliver an intervention that affects them.

- Within ARTEMIS, the anti-stigma campaign is guided by the AEAG and informs the components of the anti-stigma campaign.

- The AEAG has been suggesting contextually relevant modalities of delivering the anti-stigma campaign

Methods

- Formation of Adolescent Expert Advisory Groups (AEAGs) to craft the anti-stigma campaign
- Three AEAGs have been constituted in both cities
- Initial contact meetings organised with adolescents
- AEAG members selected based on their interest and the quality of their participation in these pre-AEAG meetings
- Written consent obtained
- Fortnightly AEAG meetings being held
- First AEAG meeting reiterated that AEAG members were the ‘experts’


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ot with my Galaxy A30

Results

- AEAG meetings yielded rich discussions and suggestions from adolescents

The AEAG suggested a mix of :

✓awareness raising to tackle lack of information on mental health, and

✓ sensitization events to force an examination of biases and its impacts on the mental wellbeing of adolescents

- Findings from the formative research showed that all anti-stigma materials were well received and effectively communicated messages

Rohit – our AEAG member

The George Institute
for Global Health

Lessons learnt

- The process of co-creation is an empowering one for the adolescents who are part of it
- The process of co-creation ensures that the intervention is culturally and locally relevant thereby making it more inclusive and therefore potentially more scalable
- Co-creation also made it possible to source adolescents with lived experience of mental disorders easily, contrary to the experiences of earlier projects
- Ethical dilemmas faced were resolved by engaging in discussions with the adolescents themselves and arriving at an acceptable solution that did not compromise on ethical principles

Conclusion

- The AEAGs have strengthened adolescent-practitioner-researcher collaboration and partnership that has provided useful insights and enriched the programme
- The process of co-creation has ensured that ARTEMIS is culturally and locally relevant thereby making it more inclusive and therefore potentially more scalable
- While conducting research with children it is essential to engage with them, especially if they are vulnerable and marginalised, and find solutions to ethical dilemmas that are acceptable to them.
- It is importance to maintain a balance between protect the interest of children and young people and recognise ‘their right to exert their competence’

Thank you!

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TIME TO LISTEN: RESPONDING TO YOUNG PEOPLE TALKING ABOUT CLINICAL RESEARCH

PANEL DISCUSSION

Moderator:
Dr. Thierry Lacaze
University of Calgary
Canada

Guest Speaker
Ms. Sheila Varadan
Independent Child Rights
Legal Researcher
Thailand

Guest Speaker
Dr. Min Soo Park
Severance Children's Hospital
Korea

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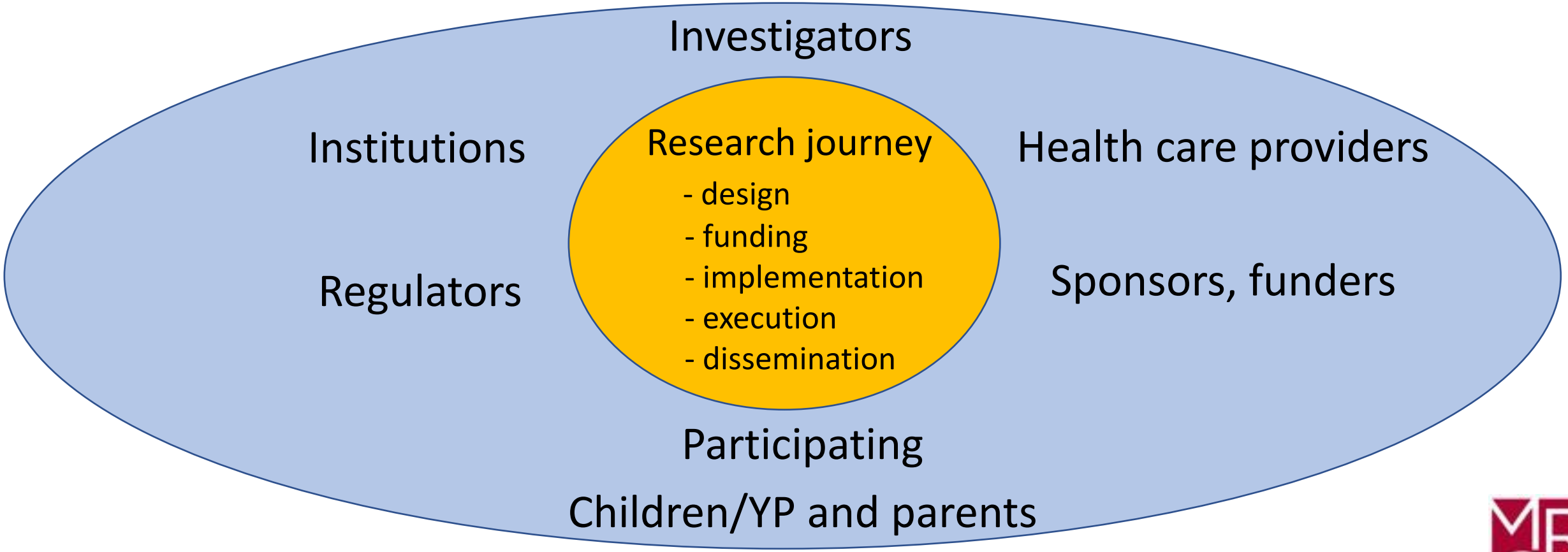
Clinical Research with Children and Young People: Different and Conflicting Perspectives



Protecting children and young people through research, not from research

- How can we ethically undertake the research needed to ensure children and young people healthcare services are safe and effective, given that research often involves burdens and risks?
- Moreover, what role should children, young people and parents themselves play in influencing how research studies are carried out, and how can their voices help influence the wider research agenda?

Quoted from Executive Summary, Children and Clinical Research: Ethical Issues. Nuffields Council on Bioethics, 2015.

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Guest Speaker

Ms. Sheila Varadan

Independent Child Rights Legal Researcher

Thailand

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Talk directly to the child

Every child is an individual and an independent rights-holder

'I really don't like it when they talk to the adult but they don't talk to me because it is as if they think my opinion doesn't matter'
(Megan, USA, 11 years)

'When I am the one who is ill, why is the doctor not discussing it with me?'
(Sandhya, India, 18 years)

'If I was younger, maybe I should not listen to all of it'
(Jan, Spain, 16 years)

Talk directly to the child

Every child is an individual and an independent rights-holder

UN Convention on the Rights of the Child

A legally-binding instrument under international law

Most ratified treaty in history – adopted in 1989 – 196 States parties

All children, even very young children, are individuals and rights-holder under international law

Children should be treated as **active participants** and **collaborators** in research –

- Right to be **HEARD** (Art 12(1))
- Right to **FREEDOM OF EXPRESSION** (Art 13)
- Right to **ACCESS INFORMATION** (Art 17)
- Right to receive guidance and support that enables their **EVOLVING CAPACITIES** in decision-making (Arts 5 and 18)

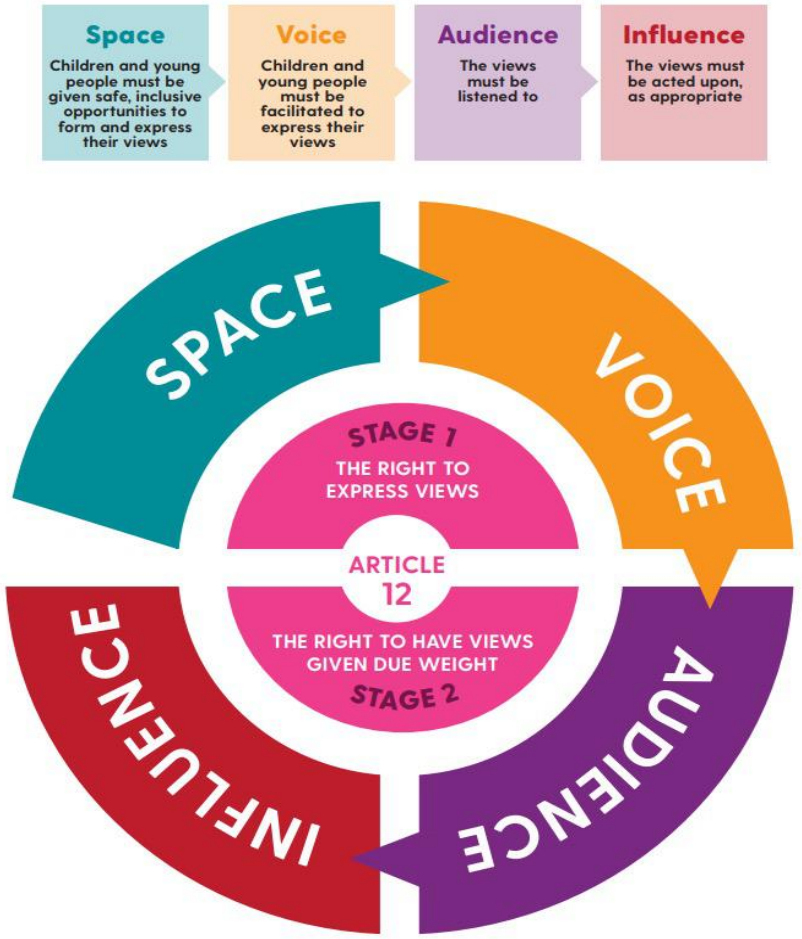
Accessing the 'child voice'

Children have a right to be part of the decision-making process

- *'We kids need to recognize the difference between people who say they are listening…and people who say they are listening and actually are'*
  (Megan, USA, 11 years)

- *'I have been part of programs that do a good job listening to the voices of children… They take our opinions and incorporate them into their programs'*
  (Sandhya, India, 18 years)

- *I am in Kids Barcelona so…I am really being heard because I am in an advisory group. Doctors and specialists come to us when they have questions they want us to answer'*
  (Jan, Spain, 16 years)



Adapted from the Lundy Model of Participation, Lundy, L. (2007) 'Voice is not enough: conceptualising Article 12 of the United Nations Convention on the Rights of the Child' *British Research Journal* 33(6) 927 – 942.

Really listen to kids

Accessing information, expressing views and having those views taken seriously

'I like it when they use visual information, like videos which help me understand the medical procedures…'
(Jan, Spain, 16 years)

'I understand the most when I am actually talking to someone. I can say something back and they can fill me in on more if they need to'
(Megan, USA, 11 years)

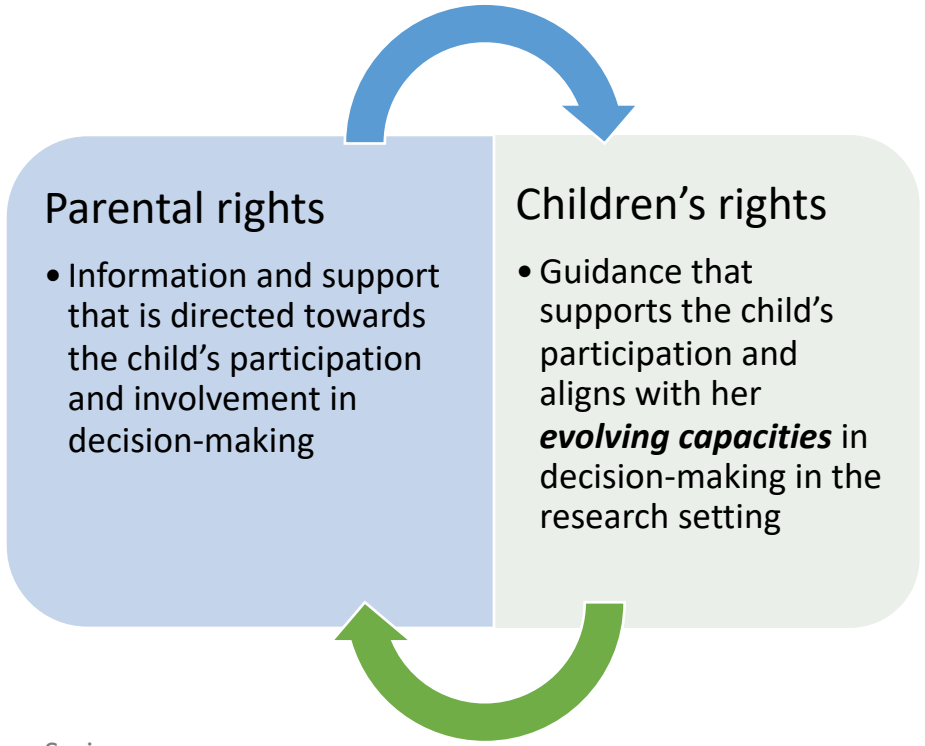
'Body language, the way of talking and the environment should build confidence in the child'
(Sandhya, India, 18 years)

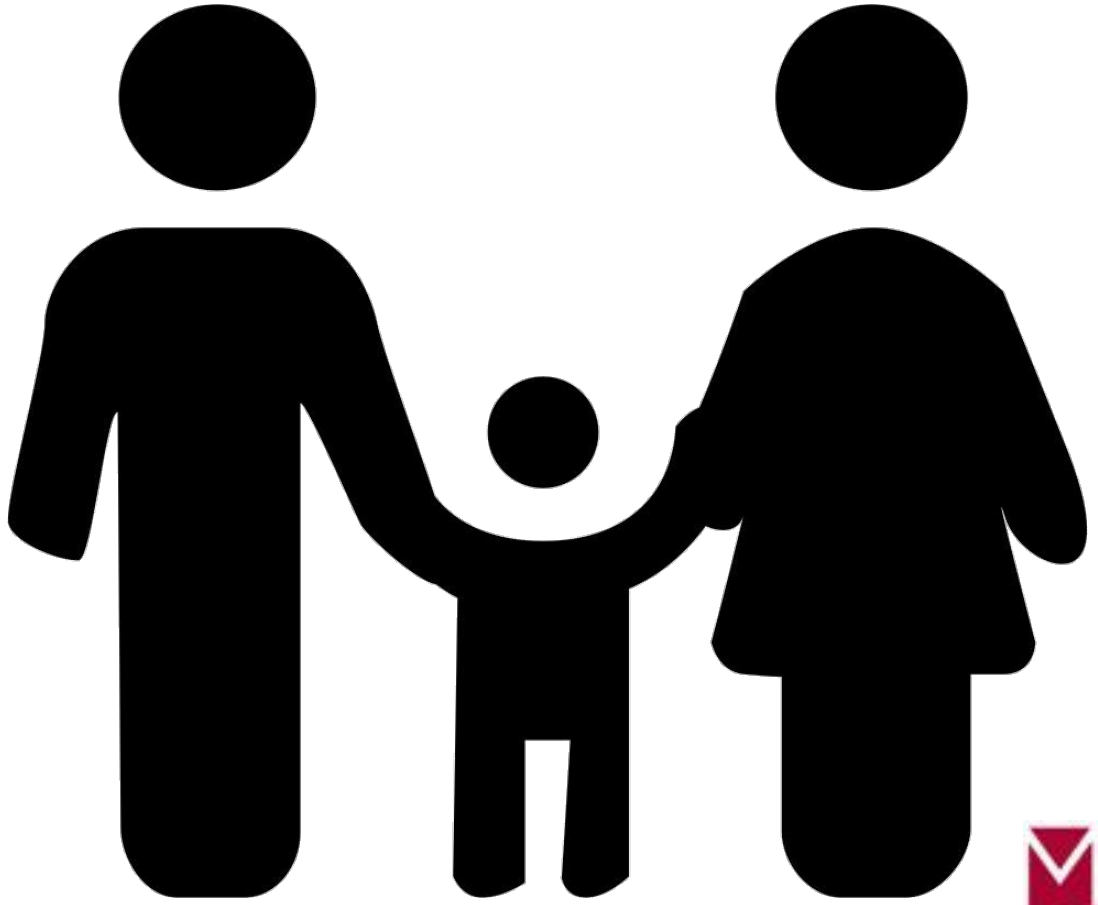
Everyday Spaces Checklist, see Government of Ireland, 'Participation Framework: National Framework for Children and Young People's Participation in Decision-Making' (2020) Available at: https://hubnanog.ie/wp-content/uploads/2021/04/5587-Child-Participation-Framework_report_LR_FINAL_Rev.pdf

Supporting parents and carers

Parents and carers are part of the information-delivery process

- *'It is essential for parents to understand as well as the childreh, because the parents are the one who know their son or daughter'* (Jan, Spain, 16 years)





Remember what it was like to be a child

Children are not the people of tomorrow, but people today. They are entitled to be taken seriously. They have a right to be treated by adults with tenderness and respect, as equals. They should be allowed to grow into whoever they were meant to be. The unknown person in side each of them is the hope for the future.

-- Janusz Korczak (1878 – 1942)

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Guest Speaker

Dr. Min Soo Park

Severance Children's Hospital

Korea

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February 2, 2022

And in closing…

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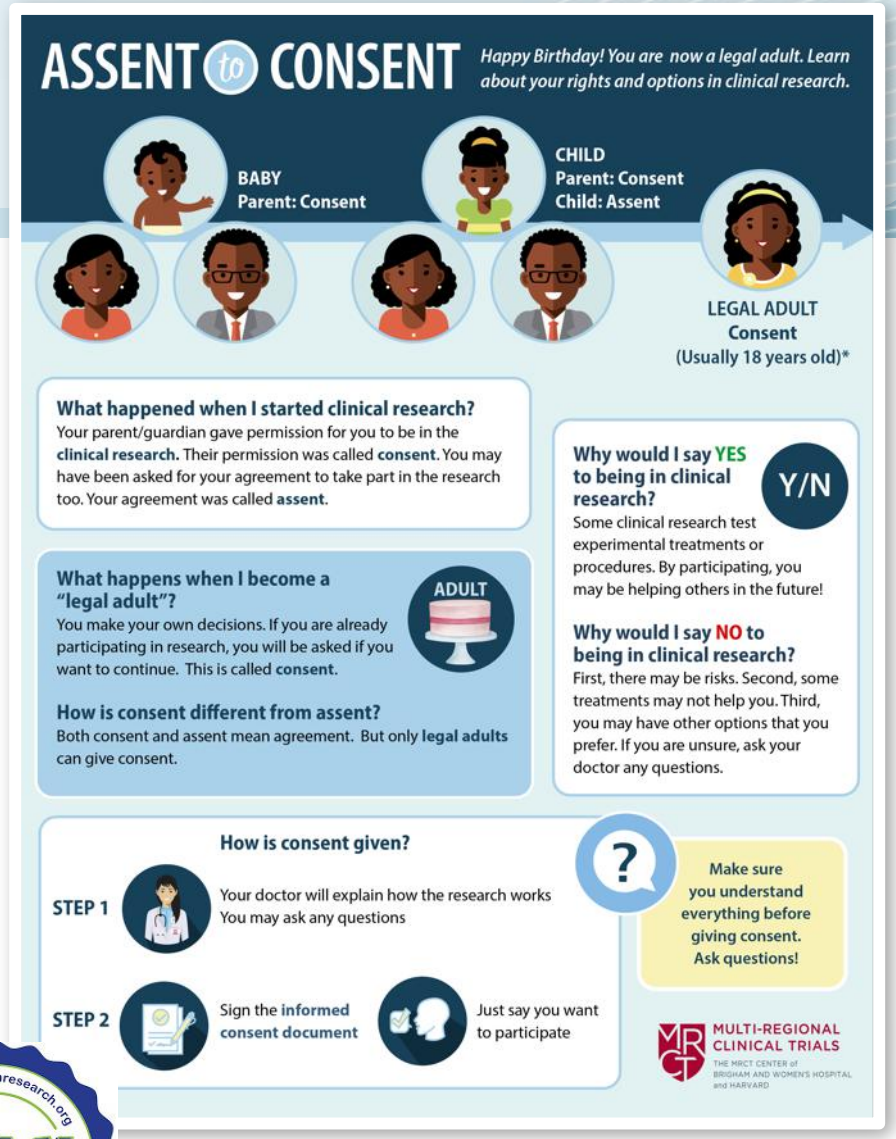
Inclusion

- Age-appropriate materials for young people considering participation in clinical trials
- The MRCT Center is developing a suite of educational materials for youth aged 12-17 (age 7-11 pending) to address that gap in accessible general information about clinical research.

All materials were developed by youth and reviewed by young people's advisory groups and international stakeholders.



Educational brochures: created by youth, for youth

- What is clinical research?
- What is assent?
- What happens at the end of the study?
- Assent to consent.

In development:

- Sharing your information (data) in research
- What is a Focus Group and Why Should I Join One?
- Sensitive Information in Research

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WHAT IS CLINICAL RESEARCH?

A guide for young people.

I've heard my doctor and my parents talking about *clinical research, clinical trials, and clinical studies*. What do these words mean?

Clinical research, clinical trials, and clinical studies are similar terms to describe ways to learn new things about how to diagnose, treat, and prevent diseases. To keep things simple, we'll just use the term research.

There are many different types of research. Some research involves testing new drugs, devices, or possible treatments for people who are sick. Other research is done to improve existing treatments, to figure out why someone is sick, or to understand how to prevent someone from getting sick.

Think of all the medicines and vaccines that keep you healthy. They were all tested on people — and some on children and young people — in research.

Who leads research?

People who lead research are called investigators. Doctors, scientists, and others can be investigators.

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WHAT IS ASSENT?

A guide for young people.

Assent means to agree.

Some research studies only need the parent's agreement —called consent—for a child or adolescent to participate. Other studies also need the child or adolescent's agreement —called assent. This brochure applies only to studies that need assent.

What should I know before I agree to join a research study?

You should know WHY the research is being conducted and WHAT you will be asked to do as part of the research study. For example, you may be asked to take a new medication or visit a research site once a week.

You can ask your doctor or the research team any question that you have about the study.

Here are some sample questions you could ask the research team:

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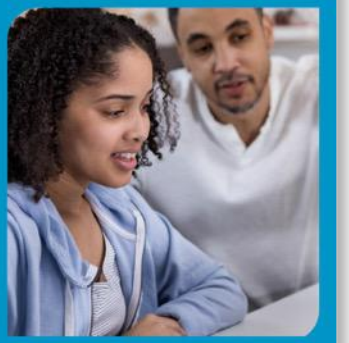
WHAT HAPPENS AT THE END OF A RESEARCH STUDY?

A guide for young people.



You are "done" with research when the investigators finish collecting information from you.

THANK YOU for taking part in research! Your contributions should help others.

What happens after my time in the study is over?

You are not forgotten! You and the research staff can still contact each other with questions that come up later. You will still see your own doctor(s) for regular medical care.

The study may still be going on for other research participants. Even if investigators have finished collecting all the information they need, the research study is not over until they have organized the information and figured out what it means.

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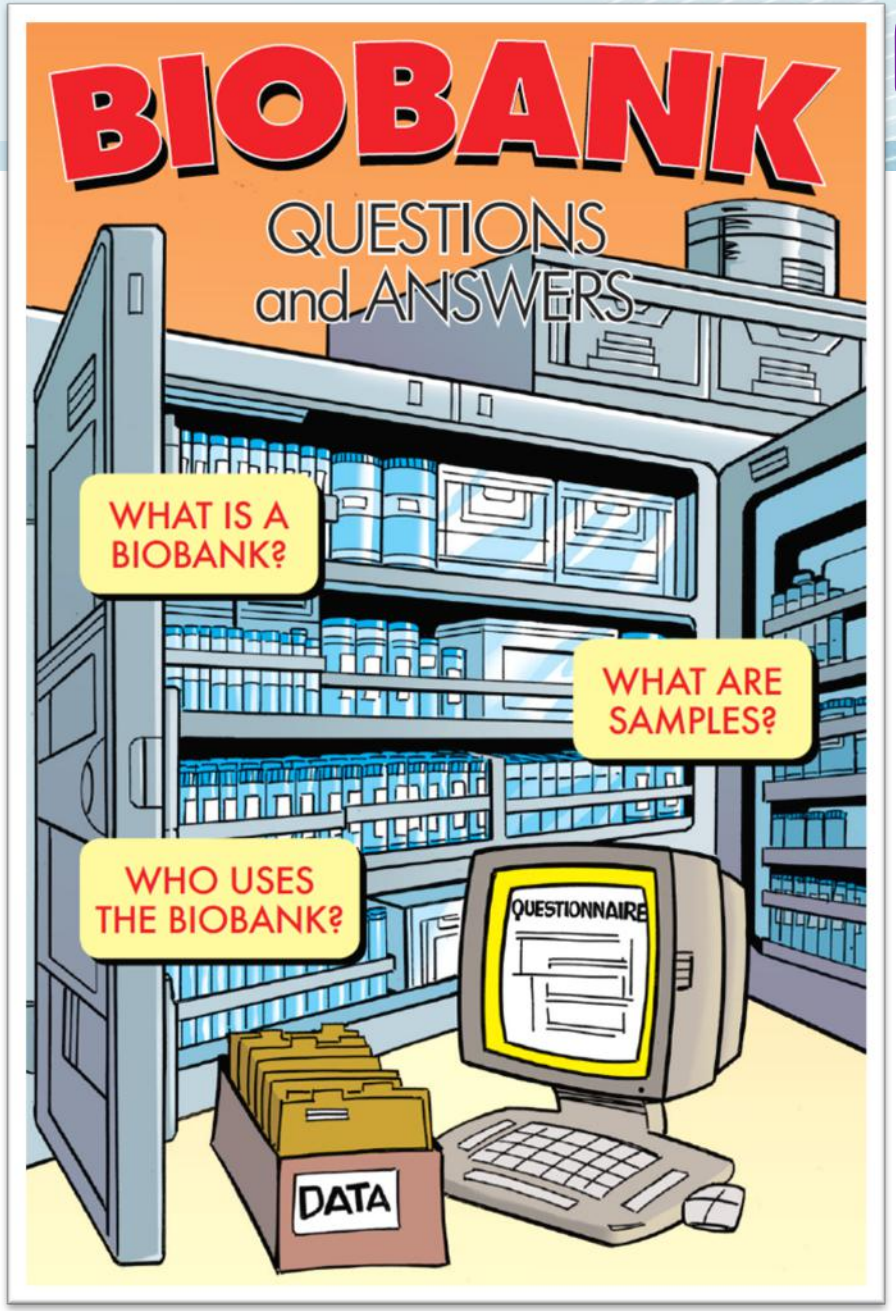
Age appropriate

In collaboration with Boston Children's Hospital and Harvard Catalyst (CTSA)



https://catalyst.harvard.edu/services/rsa/

INCLUDING YOUNG PEOPLE IN RESEARCH: A TOOLKIT

Resources to facilitate & support inclusion of youth in (non)-research activities

Meaningful Engagement: let's move beyond checking the box

- Youth participation *assent* and parental/guardian *consent* form for non-research activities
- Process considerations for pediatric patient engagement in non-research activities
  - Preparation and understanding
  - Right to review materials before and after
  - Privacy and security considerations
  - Transitions before and after engagement
- Questions offered to help stimulate consideration and adaptation to the specific context, including:
  - Initiating the conversation with young people, their parents/guardians, and caregivers
  - Youth engagement throughout the product lifecycle
  - Considerations to aid decisions around youth engagement

INCLUDING YOUNG PEOPLE IN RESEARCH: A TOOLKIT

Resources to facilitate & support inclusion of youth in (non)-research activities

Instructions for use

Youth participation *assent* and parental/guardian *consent* form for non-research activities

Instructions

- This template is designed for organizations asking youth/young adults to contribute to activities other than direct participation in research, such as a conference, advisory group, video, or focus group.
- It is not to be used as an assent form for research participation.
- It is written for anyone over the age of approximately seven.
- Please note that the << areas inside the arrows >> should be filled in with the appropriate text modified for the planned activity and the age of the child.
- When the form is printed or finalized, the arrows should be removed.
- The conversation with the adult seeking permission should occur before the conversation with the child or young adult. Only if the parent/guardian agrees should the child or young adult be asked.
- This form should NOT replace a conversation with the child or young adult.
- The assent of the child or young adult is required and should be documented.
- The parent or guardian must sign the consent for the child's participation.
  **Certain exceptions may apply*

Below we include the Privacy Statement applicable to the MRCT Center and our affiliated institution. We recommend that you adapt this statement for your institution, organization, and location, and to be consisent with regional, national, and local laws, regulations and policies.

Your privacy is important to us. This Privacy Statement explains how the Multi-Regional Clinical Trials Center of Brigham and Womens Hospital and Harvard will collect, use, and share information about those who use our platform, access our newsletter, or receive communications from us. **Learn More**

Additional EEA privacy disclosures supplement the MRCT Center Privacy and Terms of Use. These disclosures apply only to how we collect, use, and share the Personal Data of individuals located in the European Economic Area (EEA). **Learn More**

Mass General Brigham Website Privacy statement

Parent/Guardian/LAR Consent

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I'M IN:
Youth participation assent form for non-research activities

Part 1: Parent/Guardian Consent for Minor Child to Participate

Your child has been asked to participate in << activity>> at <<organization>> and will be asked to give assent to do so. The information in Part 2 includes both the specifics of the activity and the information that will be shared with your child. Please read and review the entire form before you sign.

In brief:

Additonal information about the requested activity:

Please fill out and sign this form if you agree to allow your child to participate in **<<** activity**>>**. You will be given a copy of this form to keep after you have signed it.

Have you read the assent and this consent form or it has it been read to you?
Yes_____ No_____

Have all of your questions about the form and the activity been answered?
Yes_____ No_____

Do you understand the activity your child is going to participate in?
Yes_____ No_____

Do you agree to allow your child to participate in this activity?
Yes_____ No_____

[Include any of the following questions that are applicable to the specific activity.]

Do you give us permission to audiotape your child's <<presentation, e.g.>>?
Yes_____ No_____

Young Person's Assent

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I'M IN:
Youth participation assent form for non-research activities

Part 2: What are we asking?

We are asking you to join us to participate in this << conference, advisory group, video, or focus group>>.

This sheet talks about the << conference, advisory group, video, or focus group>> and the choices that you have. We want you to ask us any questions that you have, at any time.

Important things to know...

- You get to decide if you want to take part.
- You can say 'No' or you can say 'Yes'.
- No one will be upset if you say 'No'.
- If you say 'Yes' now, you can always say 'No' later.
- You can say 'No' at anytime.
- We will thank you no matter what you decide!

Why are we doing this << conference, advisory group, video, or focus group>>?
We are doing this to find out more about [redacted].

What happens if I say yes?

- Questions: We will ask you questions about <<your experience as a XX, how you feel as a XX>>.
- Then you will say your answers.
- Recording: We will <<record your voice and face / record just your voice>>.
- <<Other>>
- It will take about <<minutes/hours>>.
- In order to get ready, we will <<talk to you before the day.>>

Use, translations, and the future of materials

- Please use and disseminate
- If you translate materials, we ask:
  - (1) Work with us
  - (2) Ensure that translated material remain age-appropriate
  - (3) Allow us to repost so that others need not expend resources replicating effort
- Please let us know if you have future suggestions for additional materials

And thank you

- Webinar recording and slides will be posted in approximate one week
- Youth videos will be also be available on YouTube
- We look forward to hearing from you
- Sign up for future webinar(s)

Special Acknowledgements

Thank you to our speakers, participants, and particularly the young people who shared their stories and taught us so much.

Dr. Gianna "Gigi" McMillan, producer of *"Time to Listen-Hearing from Young People in Clinical Research"* video

International Children's Advisory Network (iCAN), producer of "Prioritizing Young People's Voices in Clinical Research" video

All the youth who shared their time, expertise and stories with us from iCAN and Kids Barcelona

Please follow the MRCT Center

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Thank you!