Advancing International Pediatric Clinical Research

PART TWO

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

February 2, 2022

9:00AM – 11:00AM 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 in part 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

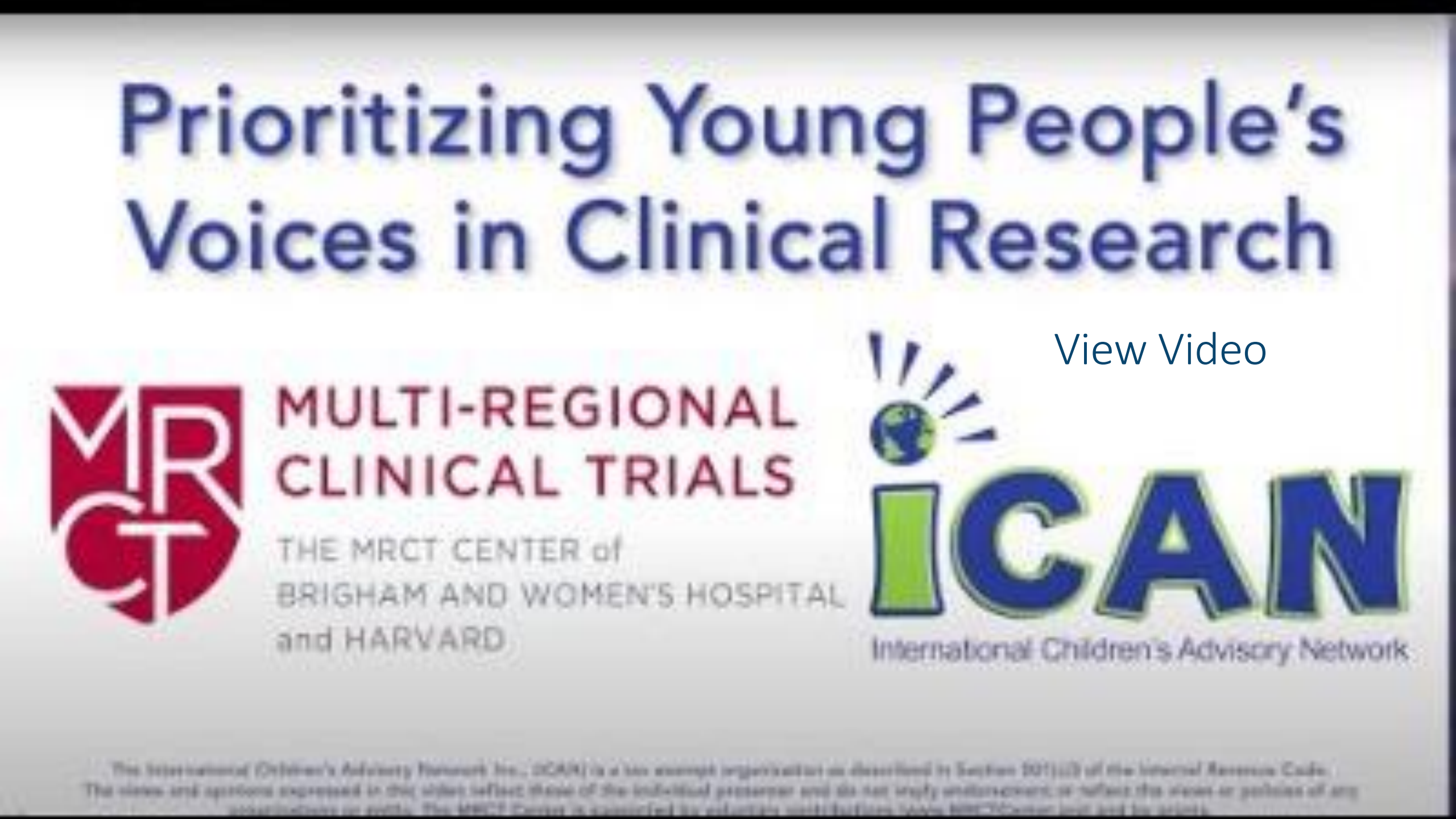
Advancing international pediatric clinical research—looking ahead

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

Ms. Jennifer Preston

University of Liverpool

England

YOUTH GUEST SPEAKER

Ms. Sophie Ainsworth

Raising Awareness of invisible Illness in Schools and Education (RAiISE)

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UNIVERSITY OF LIVERPOOL

Agents of change: listening & acting on the views of children & young people

Jenny Preston
Senior Patient & Public Involvement Manager
MRCT webinar – 2 February 2022

UNIVERSITY OF LIVERPOOL

Participation

UNITED NATIONS

CRC

Convention on the Rights of the Child

Distr.
GENERAL

CRC/C/GC/12
20 July 2009

Original: ENGLISH

COMMITTEE ON THE RIGHTS OF THE CHILD
Fifty-first session
Geneva, 25 May-12 June 2009

GENERAL COMMENT NO. 12 (2009)

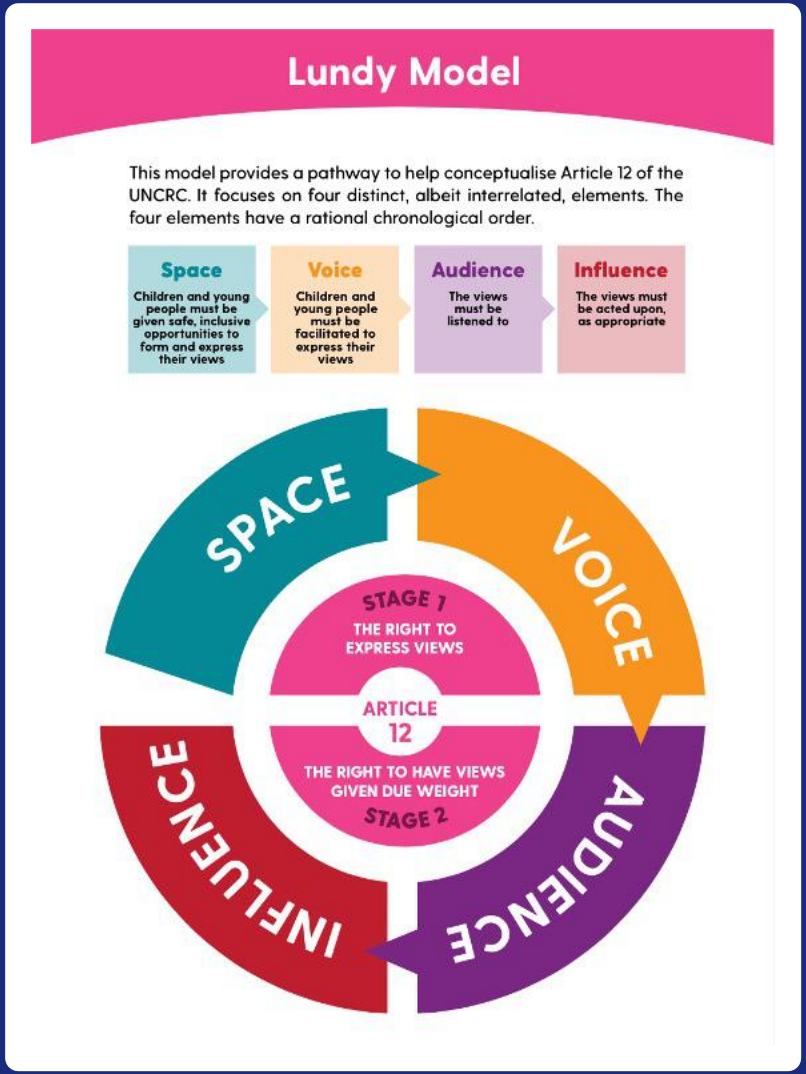
The right of the child to be heard

https://raise.co.uk

UNIVERSITY OF LIVERPOOL

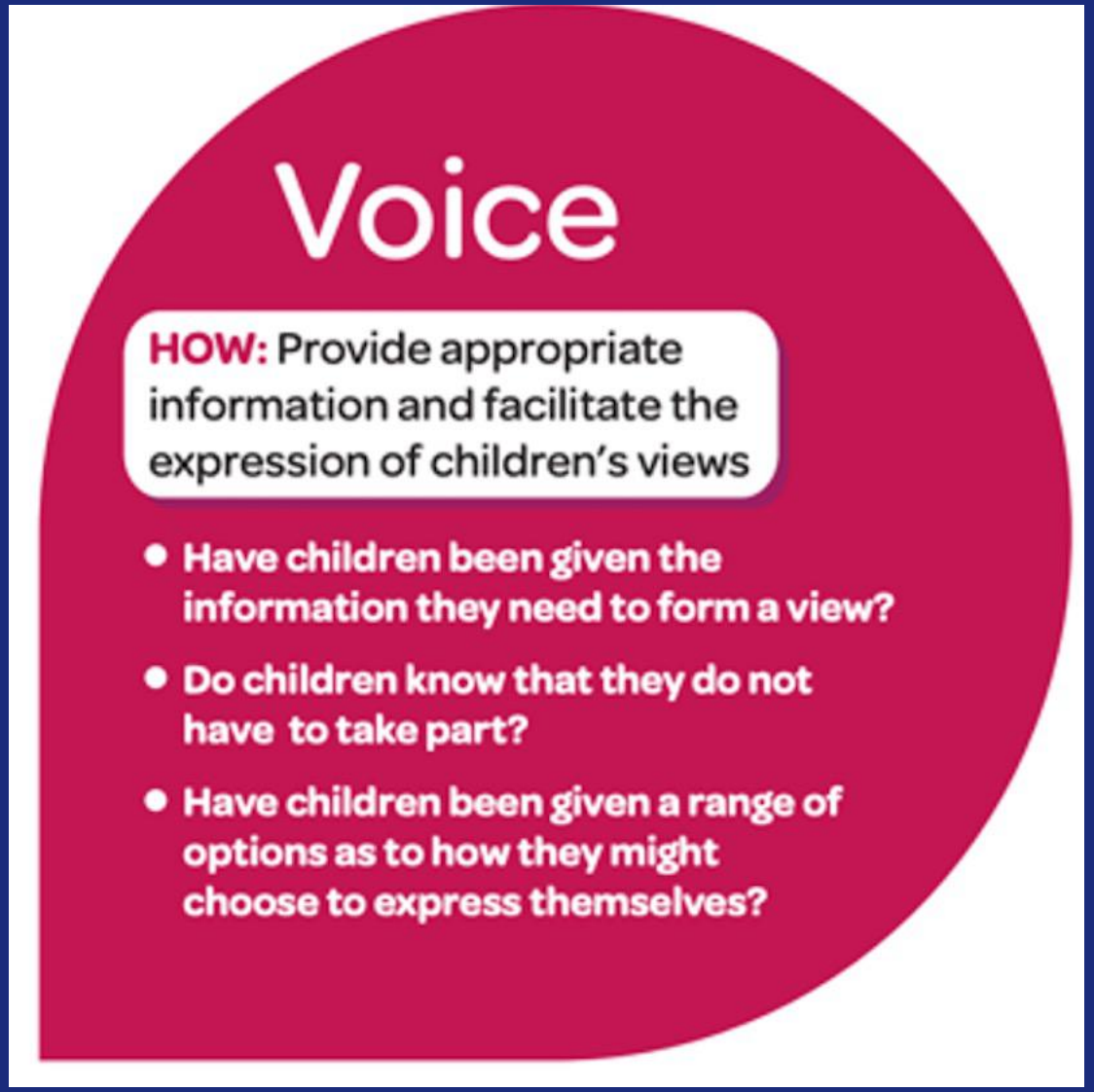
Participation with purpose

"Participation with purpose means that when children and young people are involved in decision making, their views are listened to, taken seriously and given due weight with the intention of leading to an outcome or change"
Professor Laura Lundy



" The person should be friendly and speak in an age-appropriate manner"

" Body language, way of talking & the environment helps build confidence in the child"



" I like it when they use visual information, like videos which help me understand the medical procedures"

" Sometimes I just hold it in because I'm scared that maybe I will appear stupid"

" Building good relationships with doctor's, research teams empowers young people to get involved and be truly heard"

" Kids need to recognize the difference between people who say they are listening, but actually arent"

" They take our opinions and incorporate them into the program"

I consider myself to be
a visionary, an expert, a futurist,
a mastermind, and a change agent.

Which is basically
why I'm so awesome.

Jenny Preston BA (Hons)
Senior Patient and Public Involvement Manager (**NIHR Alder Hey Clinical Research Facility**)
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http://www.eypagnet.eu/

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

PANEL DISCUSSION

Moderator
Ms. Rhian Thomas-Turner
Noah's Ark Children's Hospital
Wales

Guest Speaker
Ms. Angela Kyalo
KEMRI Wellcome Trust Programme
Kenya

Guest Speaker
Ms. Begonya Nafría Escalera
Sant Joan de Déu Children's Hospital
Spain

Guest Speaker
Ms. Erin Moore
Patient Advocate
USA

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KIDS Barcelona.. A great team!!!

Working for the design of better medicines for children!

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February 2, 2022

And in closing…

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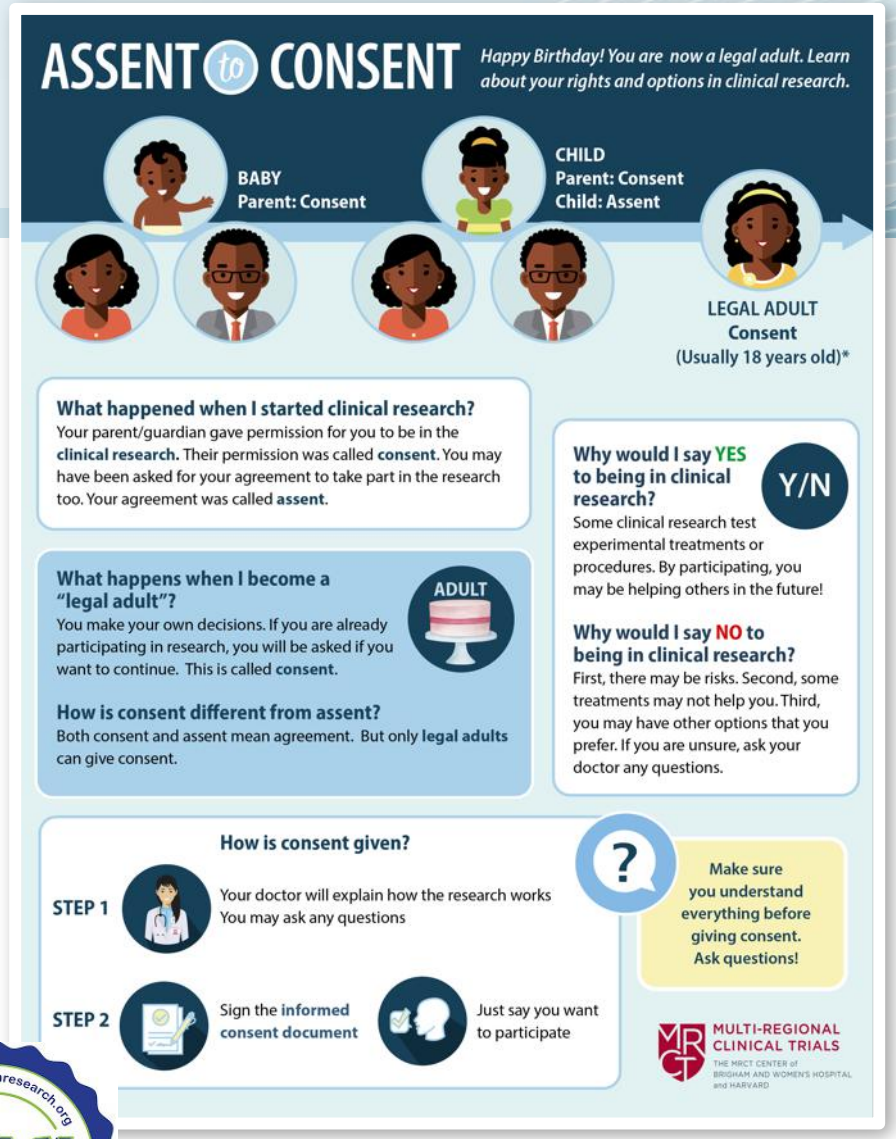
Inclusion

- 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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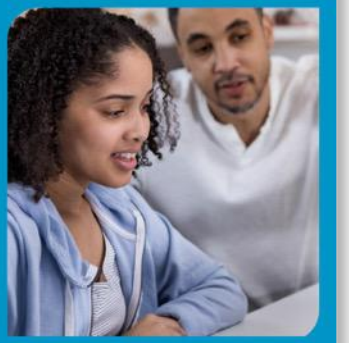
WHAT HAPPENS AT THE END OF A RESEARCH STUDY?

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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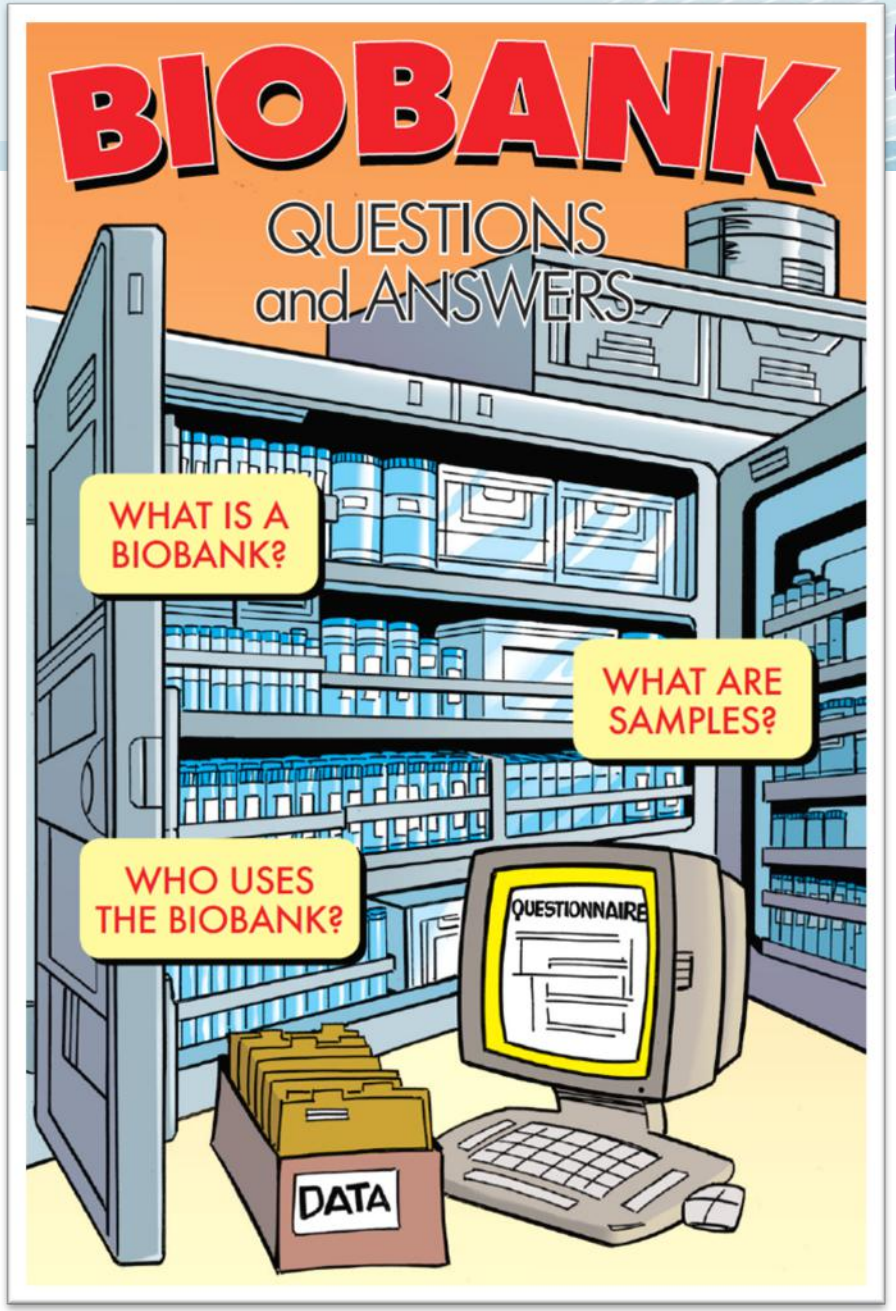
Age appropriate

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!