Talking with teens:
Clinical research educational brochures for youth

Lisa Koppelman
Program Manager,
The MRCT Center
ekoppelman@bwh.harvard.edu

Panel Discussion:
Research with Children: Parental Permission and Assent and Child-Centric Trial Education

@MRCTCenter
Talking with teens: Clinical research educational brochures for youth

Lisa Koppelman
Program Manager, The MRCT Center
ekoppelman@bwh.harvard.edu

@MRCTCenter
Disclosure: Lisa Koppelman

“I have no relevant personal/professional/financial relationship(s) with respect to this educational activity”

The Multi-Regional Clinical Trial Center

Lisa Koppelman

Program Manager
The opinions contained herein are those of the authors and are not intended to represent the position of Brigham and Women's Hospital or Harvard University.

The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities and well as by grants (see www.MRCTCenter.org).

We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables.

We will be recording this meeting only for the purpose of taking notes. The written short summary of the meeting will be shared with speakers before posting publicly.
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

Scope of the problem:

- 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
- Pediatric **market is small** but important
- **Persistent ethical issues**: while governing ethical principles may be generally agreed on, differences in interpretation and application of principles exist
- Differing or nonexistent pediatric **regulations**
- Challenges in **trial initiation and conduct**
Promoting Global Clinical Research in Children

Diverse and Representative Workgroup:
- Health Regulatory Authorities
- Academic Medical Centers
- Industry
- Trade and Professional Associations
- Research Institutes & Not-for-Profits
- Patient Advocacy

Leadership:
- Barbara E. Bierer, MD
- Sharareh Hosseinzadeh, MSc
- Steven Joffe, MD, MPH
- Dominik Karres, MD, CPM
- Gianna McMillan, DBe
- Robert Nelson, MD, PhD
- Elisa Koppelman, MSW, MPH
- Walker Morrell, MBe, BS

Subgroup #1: Decision making for children’s participation in biomedical research
Subgroup #2: Benefit/risk considerations for pediatric research
Subgroup #3: Challenges in Implementation of global pediatric clinical trials
Project foci

- Conceptualizing a better model of cooperation and transparency
- **Creation of educational resources for pediatric clinical research**
- Meaningful Patient Engagement: moving beyond checking the box
  - How best to gather and reflect the input of the child and parent/guardian
  - How to strengthen and integrate the position of the child and parent/guardian
  - How to solicit and hear young people’s voices
  - What is representative and sufficient input?
While scoping the problem, we found gaps in availability of materials and easy access.

Decided to fill some of those gaps.

We looked at the lifecycle of clinical research and targeted areas specific to youth.

A HS intern worked closely with our team to develop materials.

Materials were drafted, reviewed and vetted materials with several youth advocacy organizations both in and outside US.

Proud to display the iCAN Seal of Approval for the first in the series, Assent to Consent, with 6 more in development.
Project evolution

- Age-appropriate materials for young people considering participation in clinical trials was lacking.
- The MRCT Center developed a suite of educational materials for youth aged 12-17 (age 7-11 pending) to address a gap in accessible general information about clinical research.
- Current topics include
  - Explanation of clinical research
  - Assent
  - Data privacy and risks
  - Expectations and risks of focus group participation
  - Others

All materials were developed by youth and reviewed by young people’s advisory groups and international stakeholders.
Accessible pediatric focused educational materials that provide necessary information about select aspects of clinical research for young people are lacking.

We sought to address this gap by developing brochures—created and vetted by youth—targeting 12–17-year-olds that explain critical aspects of participation in clinical trials.
Make it fun

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

https://catalyst.harvard.edu/services/rsa/
These health-literate, age-appropriate resources are available publicly (https://mrctcenter.org/blog/resources/pediatric-research-informational-materials/) continuously updated, and disseminated through an international network of children’s hospitals, researchers, and youth advisory groups.

These educational materials fill a gap in clear communication to youth regarding clinical research.

Easily accessible via download and linked from multiple youth focused sites, these materials, by young people and to young people, speak to youth in ways not available elsewhere.

Each of the resources has been reviewed and edited by existing youth advisory networks, and we will continue to gather feedback to propel iterative improvement.

As the materials are finalized, posted, and distributed, we invite further feedback.
Next steps & addressing limitations

- Current intended audience is ages 12-17 years and in the future we hope to adapt for a younger audience (children ages 7-11 years)

- Materials are currently only available in English.

- Opportunities for translation through local and global partners and others able to assist.

- We plan to adapt, as time and resources permit, to various mediums including social media.
Looking ahead

- IRBs and HRPPS can download these materials and make them available to their own research communities.

- We will promote through additional channels such as social media, presentations, child advocacy groups, children’s hospitals, pediatricians, and others.

- Networks with whom we partner, are affiliated, and collaborate have committed to dissemination.

- We invite feedback and additional collaborators to create age-appropriate information for children involved in or considering participation in clinical research.
Thank You!

Lisa Koppelman
Program Manager, The MRCT Center
ekoppelman@bwh.harvard.edu

@MRCTCenter