

GRAnD

Growing Research through Advocacy and Dedication

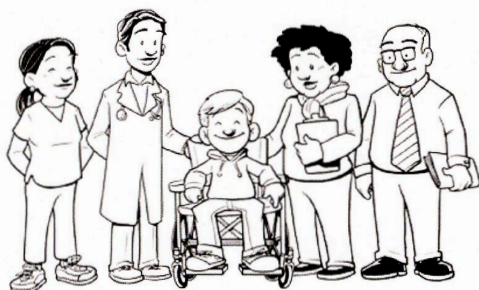
INSPIRED BY CHILDREN, DRIVEN BY SCIENCE

Who we are

Lurie Children's Vision 2025 is to become a national leader in achieving a healthier future for every child. Our group is driven by the core transformational imperatives: to advance our standing as a leading center of scientific discovery and innovation and to expand clinical capabilities to benefit more children. Growing Research through Advocacy and Dedication (GRAnD) is a Lurie Children's-based research collaboration and workgroup that consists of clinical research professionals, investigators, and IRB representatives who are committed to improving the lives of children through high impact research at Lurie Children's. We seek to create a health literacy-informed library of patient, parent, and stakeholder-driven educational tools to sustain meaningful family engagement in pediatric research.

What we're doing

We have established an engaged stakeholder network to guide the creation of educational tools that aim to increase patient and parent knowledge and understanding of complex research topics, including informed consent and participant recruitment.



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GRAnD LEADERSHIP

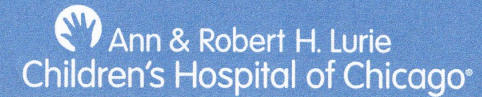
GRAnD is a multidisciplinary group of Lurie Children's research professionals spanning the spectrum of clinical, translational, and outcomes research. Leadership currently includes:

- **Fred Hebal, MD, CCRP** leads outreach to the Kids Advisory Board, Walter Payton High School, and advocates for patient engagement in the research process.
- **Jessica Macha, CIP** brings expertise in IRB administration and the protections of human subjects in research.
- **Christy Anton, CCRC** brings multi-institutional experience across all types of clinical research while seeking novel ways to engage patients and families.
- **Dhey McClure, RN, CCRC** supports advancing research with years of clinical research in various specialties and institutional knowledge.
- **Beth Kaurs, CCRP** contributes years of experience teaching researchers, children and families about clinical research to facilitate participants' enhanced understanding of clinical trials.
- **Chris Stake, DHA, CCRP** brings experience in outcomes research, proposal development and a unique perspective from her time as a Child Life Specialist
- **Jamie Burgess, PhD** supports study and proposal development with expertise in study design and competitive funding applications.
- **Stefanie McCormack, CCRP** brings industry experience in Phase II, III, and IV clinical trials and supports Lurie Children's community outreach and healthcare innovation efforts at MATTER.
- **Katherine Barsness, MD, MSCI** oversees this project and advocates for patient partners' voices to be integral to future research efforts.
- **Erin Paquette, MD, JD, MBe** contributes expertise in research ethics, including the study of efforts to improve research consent and reduce disparities in research participation.
- **Marina Arvanitis, MD, MPH** is a health literacy researcher that contributes her expertise in participant understanding of research and health-related concepts.

Patient Driven Education: A novel approach to participant engagement in the research process

Stefanie McCormack, BS; Ferdynand Hebal, MD; Jessica Macha, BA; Christy Anton, BS; Adelaide D. McClure, ADN; Elizabeth Kaur, BA; Christine Stake, DHA; Jamie Burgess, PhD; Katherine Barsness, MD, MSCI; Erin Paquette, MD, JD, MBE; Marina Arvanitis, MD, MPH.

Ann & Robert H. Lurie Children's Hospital of Chicago | 225 East Chicago Avenue, Chicago, IL 60611



Background

Respect for Persons requires subjects to provide voluntary, informed consent prior to participation in research. [1]
 Communication barriers during the informed consent process lead to misunderstandings and misconceptions. [2]
 Multimedia and interactive media improve adult understanding of research, however, *the unique needs of children and their families have often been left out of these efforts.* [3]

Purpose

To engage **children and families** in creating an animated video to demystify clinical research and aid in their decision making process.

Methods

Stakeholder focus groups with parents, children, and adolescents were conducted to:

- 1) Identify themes related to knowledge, concerns, and misconceptions of the research process
- 2) Determine which research concepts and terminology may be better explained with video
- 3) Discover children's preferred approaches to the consent process

Separate stakeholder groups consisted of:

- Students from a local public high school
- Parents of children with chronic medical conditions
- Children with serious chronic medical conditions (all members of the International Children's Advisory Network)

Stakeholder groups were re-convened multiple times to view whiteboard video storyboards and assess them on:

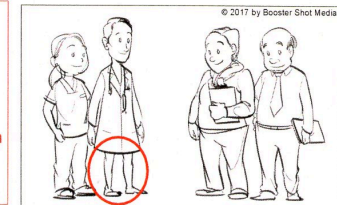
- 1) Content objectives
- 2) Clarity of concept
- 3) Appropriateness for a pediatric audience
- 4) Script comprehension
- 5) Character and animation design

Results

Focus groups provided feedback to designer on character design, storyboards, and script. Edits made by designer are shown in **RED**.

Children's Feedback: People here could use redraws because clothing and hair is unclear for roles. Suggestion – draw character as role is mentioned.

Booster Shot Media: Characters will appear as their specific role is mentioned in narration. Overall design will be improved to reflect roles.



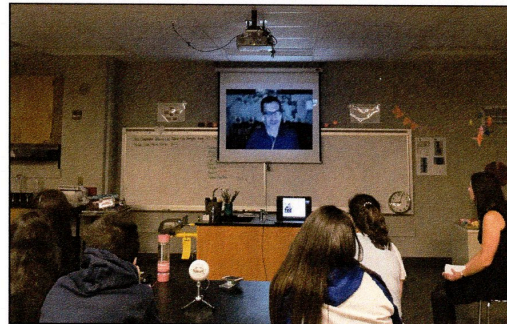
Narrator: It takes a lot of people to do medical research – doctors, nurses, research staff coordinators, and people who are trained to look at the results and see what we can learn.



Children's Feedback: What is the person on far right holding? This person is not clear.

Booster Shot Media: To make this more clear, we are going to switch this to a GI issue and the visual will be of the GI tract. We will also rearrange the order. See narration changes below.

Narrator: Questions like: What is the cause of **inflammatory bowel disease** in children? Or, can **our hospital** do better at heart surgery? Or, how do kids manage **asthma during the school day?**

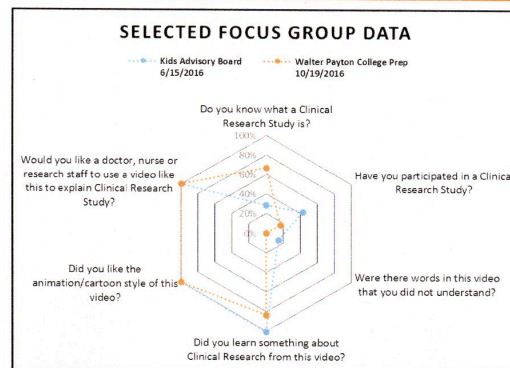


High school focus group video conference with designer.

Interested in viewing the video?
 Scan the QR code or go to the link:

English Spanish

What is Research?
 English: <https://tinyurl.com/LurieResearch>
 Spanish: <https://tinyurl.com/LurieSpanish>



Responses to selected focus group questions

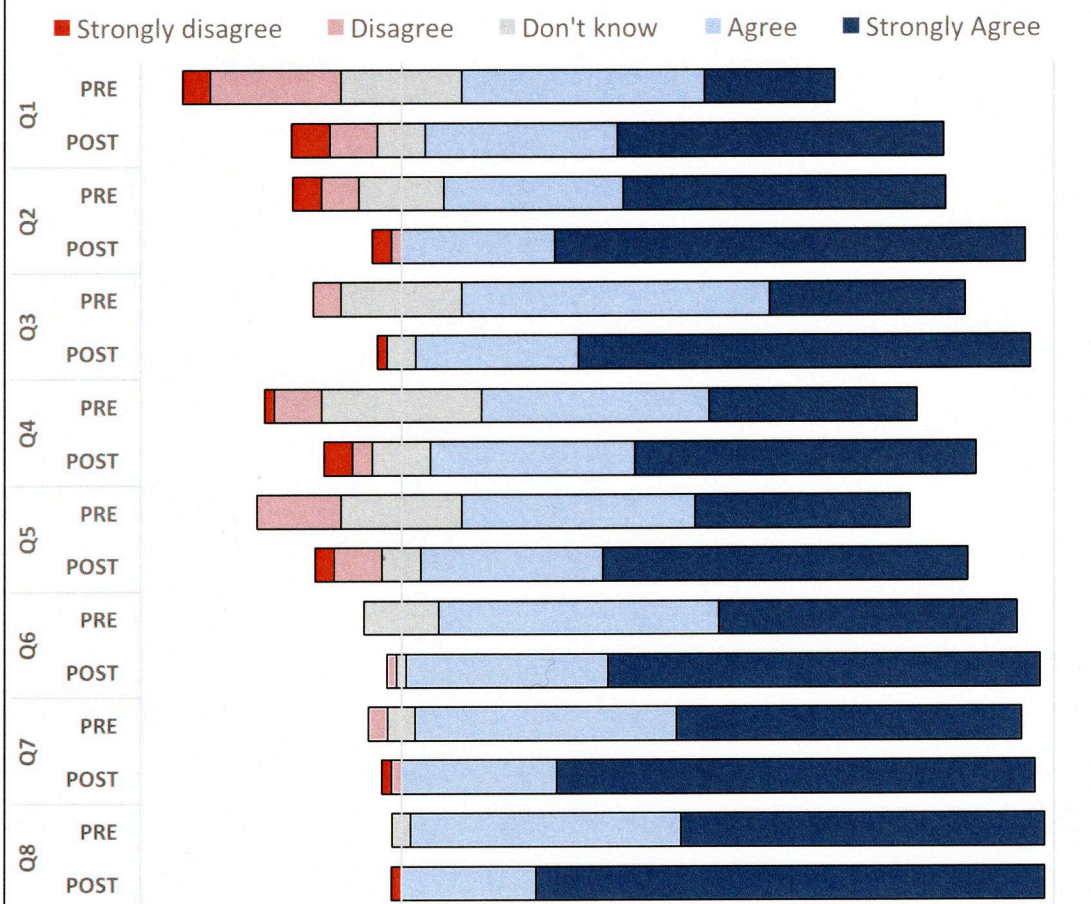
Conclusions

- Active engagement of children and families in the development of tools to address research misconceptions has the potential to improve participant understanding during the consent process.
- Feedback was directly incorporated into a pediatric-focused introductory video on clinical research titled: **"What is Research?"**
- The next steps for this initiative are to assess comprehension of the consent process enhanced by this video and to determine if the video has a direct impact on clinical research recruitment and retention.

References

- 1) "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The National Commission for the protection of human subjects of biomedical and behavioral research. April 18, 1979.
- 2) Fisher, J. A. (2006). Procedural Misconceptions and Informed Consent: Insights from Empirical Research on the Clinical Trials Industry. *Kennedy Institute of Ethics Journal*, 16(3), 251–266.
- 3) Tat, A. R., Vogel-Lewis, T., Chetani, S. J., Brennan-Martinez, C., & Levine, R. (2014). Enhancing Patient Understanding of Medical Procedures: Evaluation of an Interactive Multimedia Program with In-line Exercises. *International Journal of Medical Informatics*, 83(5), 376–384.

Likert Survey Analysis



Wilcoxon Ranked-Sign Test

Question	P-value
Q1 I have don't have to decide right away.	<.0001
Q2 I will be told what is going to happen to me during the study.	0.0004
Q3 I can decide to stop being in the study at any time.	<.0001
Q4 My doctor will not take better care of me than if I didn't join the study.	0.002
Q5 The research team cannot share my information with people not on the team.	0.009
Q6 I know that my doctors and the hospital will make sure that the study is safe.	0.0004
Q7 I can say no.	0.008
Q8 I can ask questions about the study	0.005