Making Clinical Trials and Informed Consent More Patient-Centered

Health Literacy in Clinical Trials: Practice and Impact Workshop
National Academy of Science, Engineering & Medicine

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Our Team

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Combined Areas of Expertise

- Health communication
- Health literacy
- Patient-centered care
- Patient engagement
- Human computer interaction
- Child education and intervention
- Genomics, bioethics
- Intellectual, developmental disabilities
- Graphic design
- Informatics and computing technology

Clinical Trials Now and a Vision for the Future

Consent: Traditional informed consent often falls short of several best practices.

Understanding: Participants frequently misunderstand the rationale and design of clinical trials leading to poorer informed consent (Joffe et al., 2001).

- They often sign consent forms, but don't understand them. When faced with the reality of study requirements, many drop out (Grady, 2015).

Dropout Rate: Participant dropout rates average 30% for Phase 3 clinical trials (National Research Council, 2010).

Recruitment: Globally, 90% of clinical trials fail to achieve timely recruitment of their target population (Institute of Medicine, 2010).

Health Literacy: Low health literacy is a barrier, but it is addressable.

Findings from Studies to Improve the Informed Consent Process

Comprehension was not inferior in the simplified consent form group as compared with the traditional consent form group.

(Beskow, 2016; Grady, 2017)

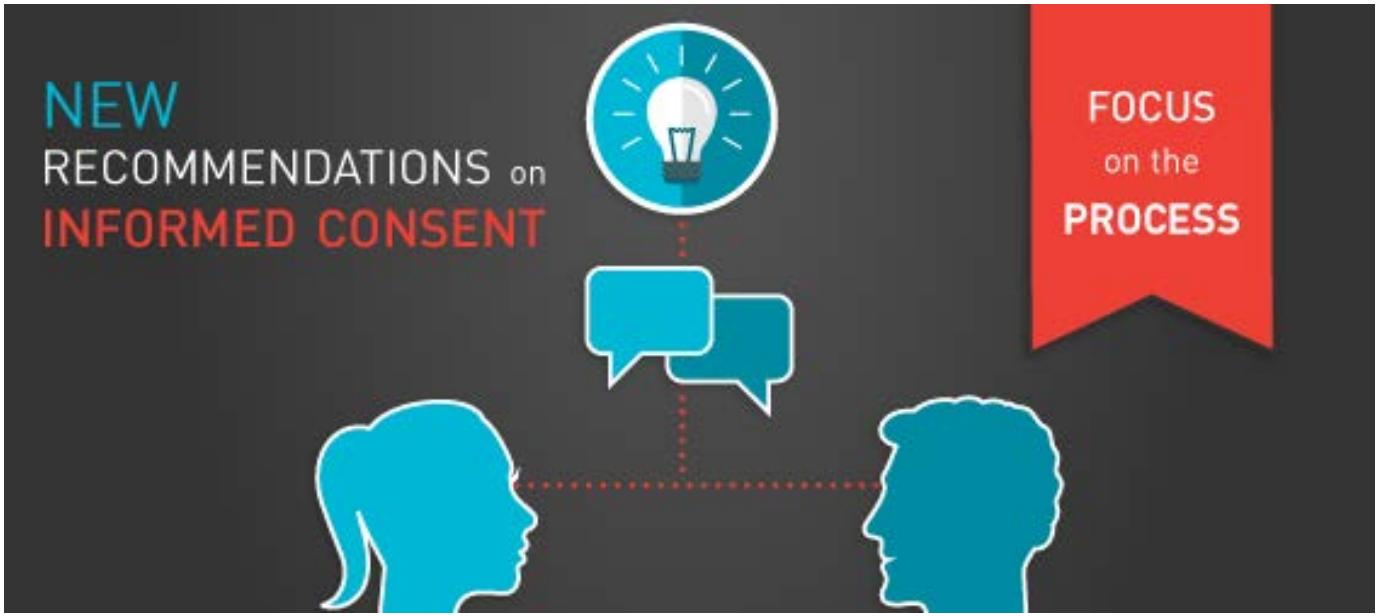
- However, the simplified version was not superior among participants with lower education. Review and retesting significantly improved test scores. (Beskow, 2016)

A simplified consent form was associated with higher levels of objective and subjective understanding regardless of health literacy level (Kim & Kim, 2015)

Use of interactive technology has the potential to improve the process of informed consent. Anderson et al., 2017)

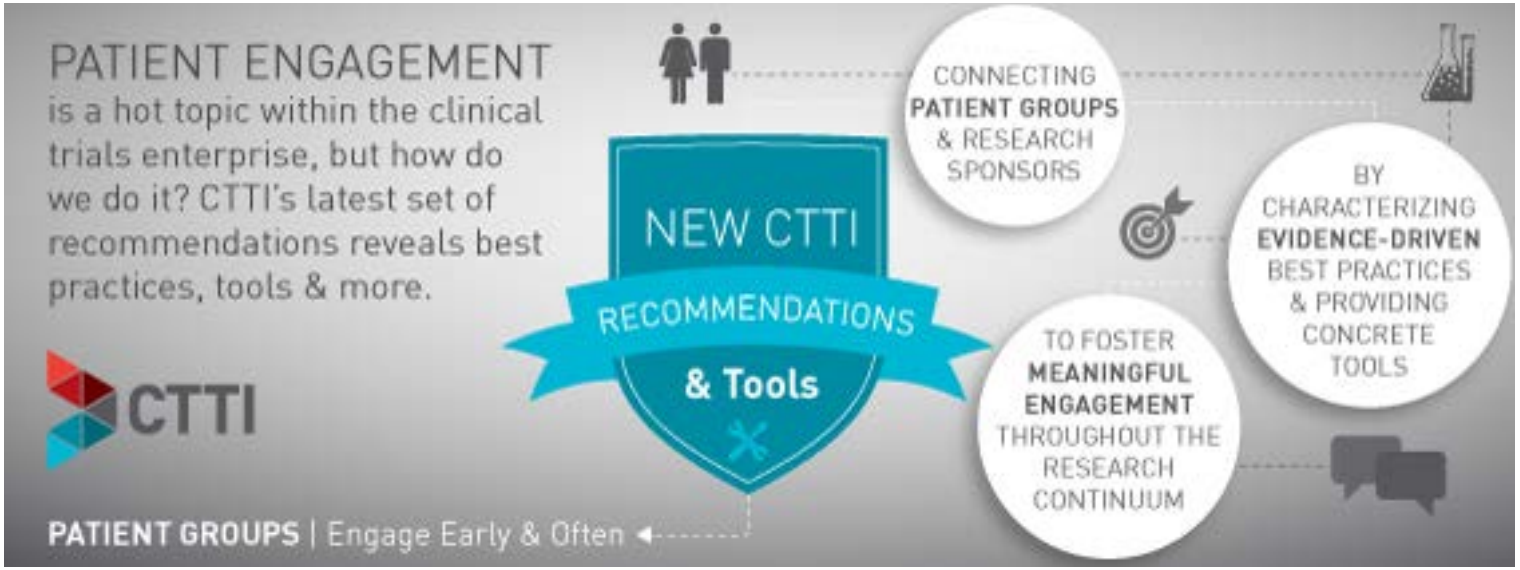
- Technology cannot replace the human connection that is central to the informed consent process (Anderson et al., 2017) In-person, one-on-one discussions may be the most effective (Flory, 2004)

Clinical Trials Transformation Initiative (CTTI)



Source: Clinical Trials Transformation Initiative, 2015a.

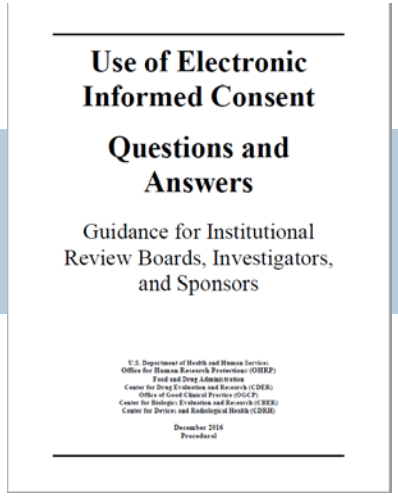
Source: Clinical Trials Transformation Initiative, 2015b.



FDA Initiatives

Patient-Focused Drug Development

- **Incorporating the patient's voice** in drug development and evaluation by…
  - Using systematic approaches to collect and use patient and caregiver input
  - Identifying and using approaches to facilitate patient enrollment and minimize burden
  - Using methods to capture information on patient preferences and tradeoffs between benefits and risks
  - Providing information most important to patient decision-making


Use of Electronic Informed Consent

Questions and Answers

Guidance for Institutional Review Boards, Investigators, and Sponsors

Electronic Informed Consent Guidance

- How and where may the electronic informed consent (eIC) **process be conducted**?
- How can **electronic signatures be used** to document eIC?
- What steps can be taken to help **ensure privacy, security, and confidentiality** of the eIC information? (FDA, 2016)

Addressing Limitations of Clinical Trials

The National Academies of SCIENCES ENGINEERING MEDICINE

Virtual Clinical Trials: Challenges and Opportunities – A Workshop

November 28, 2018; Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine

http://www.nationalacademies.org/hmd/Activities/Research/DrugForum/2018-Nov-28.aspx

Clinical Trial Innovation Summit: Patient-Centric Approaches to Data-Driven Clinical Trials

May 13-15, 2019; Cambridge Healthtech Institute

https://www.clinicaltrialsummit.com/

DIA

Drug Information Association (DIA) Global Annual Meeting

June 23-27, 2019

https://www.diaglobal.org/en/flagship/dia-2019/about/conference

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

Summit for Clinical Ops Executives (SCOPE)

February 18-21, 2019; Cambridge Innovation Institute

https://www.scopesummit.com/

Digital Clinical Trials Workshop: Creating a Vision for the Future

April 1-2, 2019; National Heart, Lung, and Blood Institute

https://www.nhlbi.nih.gov/events/2019/digital-clinical-trials-workshop-creating-vision-future

The Value of Decision Aids

Decision aids differ from usual health education materials because decision aids make explicit the decision being considered, and provide detailed, specific, and **personalized** focus on options and outcomes for the purpose of preparing people for decision making." – Stacey et al., 2014

Decision aids are…	Evidence-based tools…	Intended to help patients be active participants and…	Assist them in making specific and deliberated healthcare choices among various options.

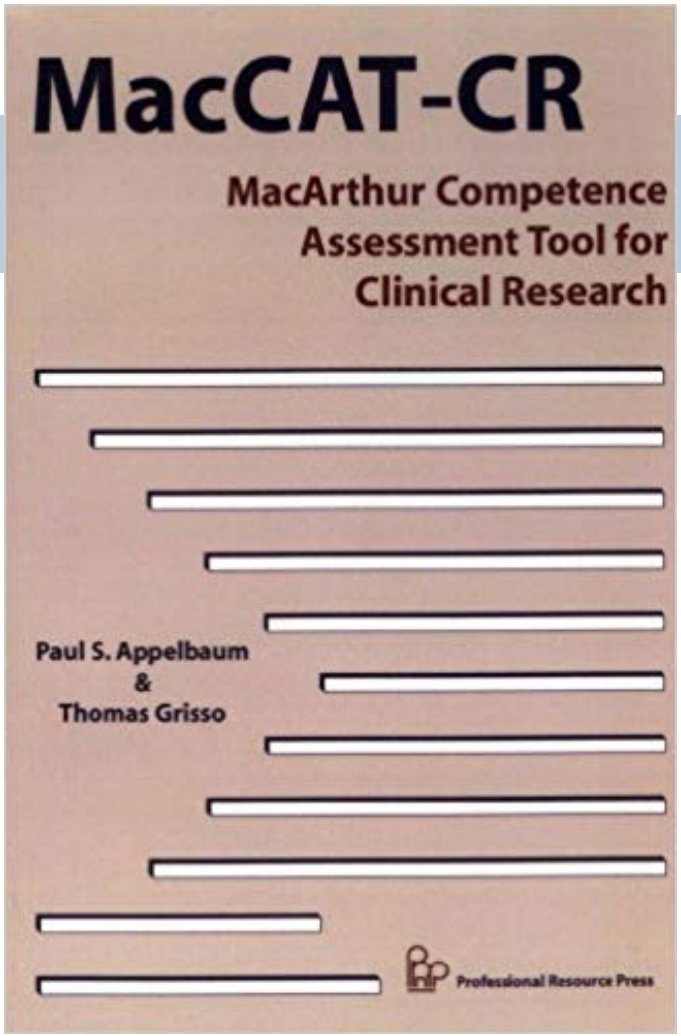
Randomized Controlled Trial to Assess Efficacy of Informed Consent Tool

- **Research Questions**:
  - Does the tool improve the capacity of individuals to make an informed decision about consenting relative to standard practice?
  - Variation by level of cognitive function?
- **Population:** Individuals with fragile X syndrome (FXS), aged 12 to 40
- **Study Design**: 2x2 experimental design with stratified randomization
- **Measures:** Understanding, Appreciation, Reasoning, Decision about trial participation

Assessing Decisional Capacity

Does the Individual…

- **Understand** the nature of the trial and its procedures?
- **Appreciate** the impact of participating in the trial on their own care?
- Use **reasoning** to decide whether they will participate?
- **Express a choice** about participating?



Source: Appelbaum & Grisso, 2001.

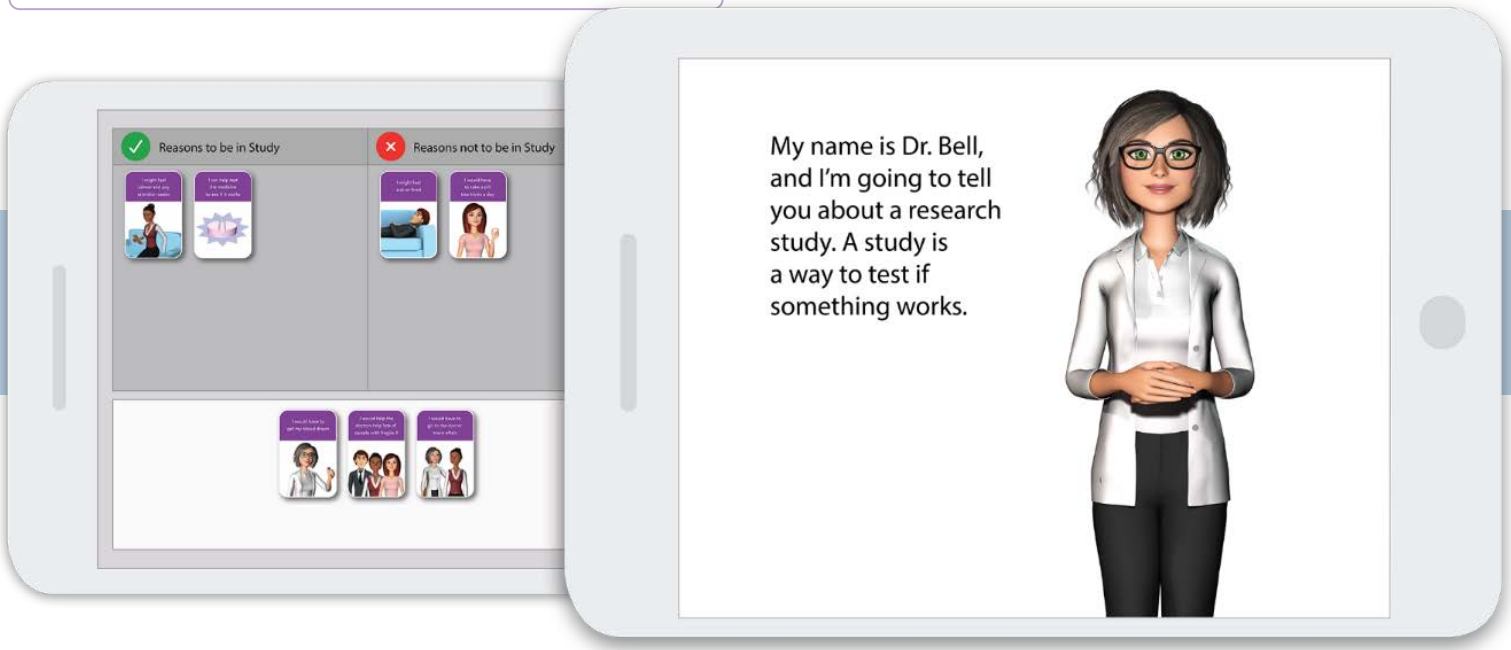
Key Strategies Applied in Tool Development

- Plain language, clear communication strategies
- Health literacy principles
- Interaction/engagement with information via:

Multimedia communication

Knowledge assessment

Values clarification exercise

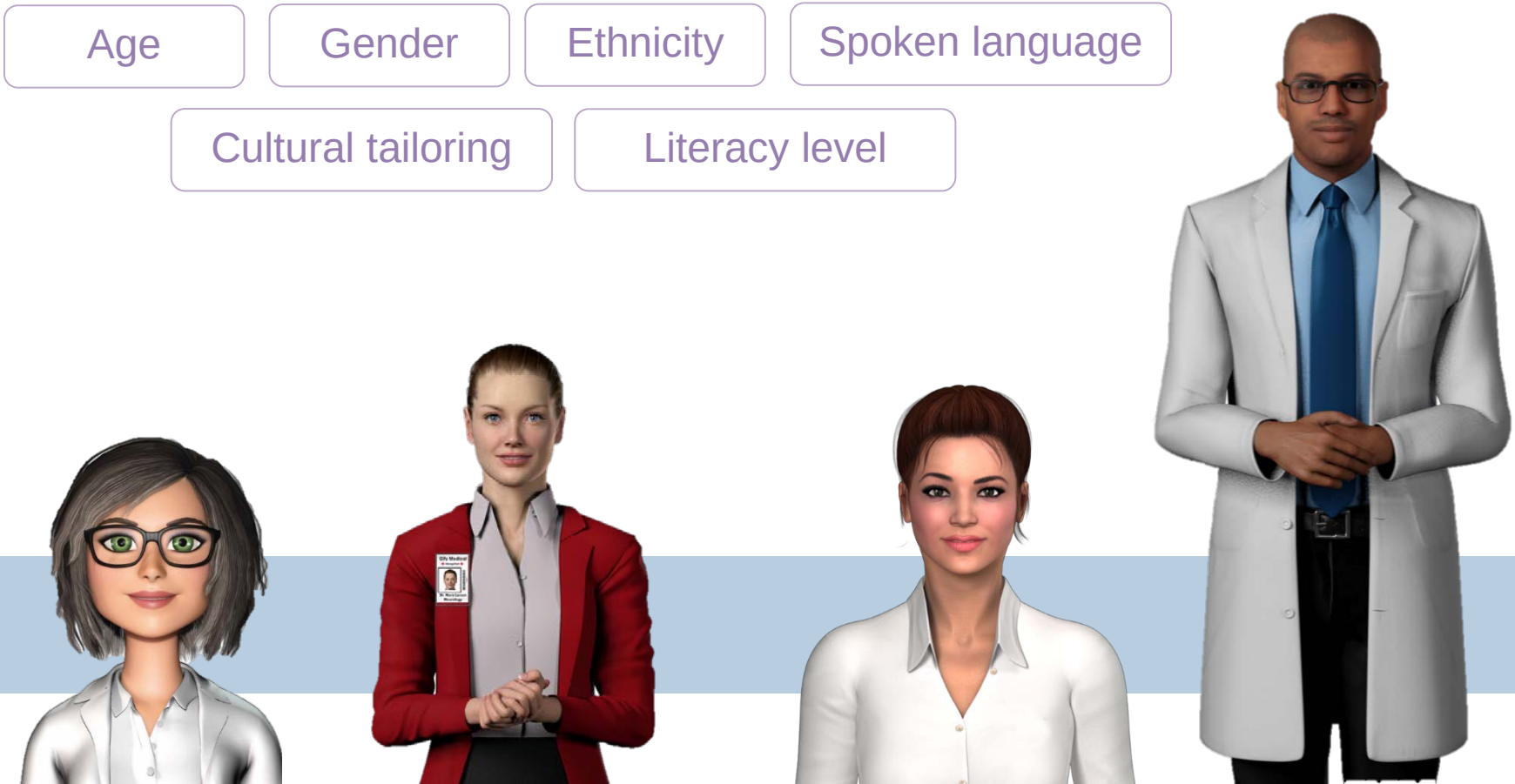


Multiple Avatars and Languages

Avatars Customized for Target Audience Who Interact with Potential Study Participants

Avatars vary by:

- Age
- Gender
- Ethnicity
- Spoken language
- Cultural tailoring
- Literacy level



Explaining the Design Elements of a Clinical Trial

Modules derived from informed consent form or trial protocol

- Includes IRB-required elements:
  - Study purpose
  - What the study involves
  - How the study works
  - Risks
  - Benefits
  - Ability to withdraw from study

Transform content

- Lower reading grade level
- Explain complex design elements and terminology

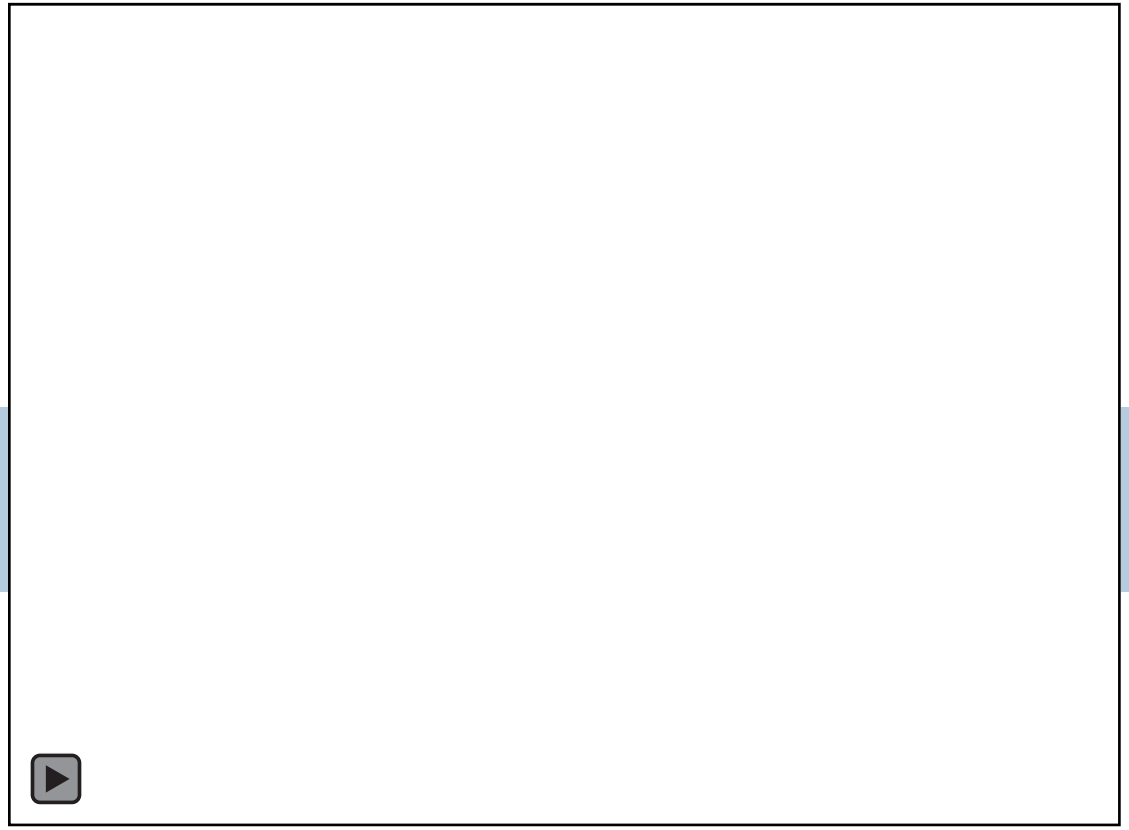
Use engaging visuals, narration, and exercise

- Guide participants through the experience

Values Clarification Exercise

- Explains the options
- Fosters the deliberation process
- Clarifies individual preferences and values

(Stacey et al., 2017; Fagerlin et al., 2013)



Example Questions

Fragile X syndrome:
Adolescent Population
(Medication RCT)

What is one thing you will do at the doctor's office?

a. Eat lunch

b. Pee in a cup

c. Get my ears checked

d. Get a shot

How often will you need to take the medicine?

a. Three times a day

b. When I am hungry

c. Two times a day

d. Only when I eat breakfast

Adults with Chronic Pain
(Patients randomized in two behavioral interventions)

What is the purpose of the study?

a. To research new medicines

b. To have patients try therapy

c. To compare two programs to see which one works better

d. To compare two medicines to see which one works better

What will happen if you no longer want to be in the study?

a. Once I join, I have to stay in the study

b. **Nothing, I can stop being in the study at any time**

c. I need to ask my doctor's permission to stop being in the study

d. My doctor will be angry

RCT Results: Understanding Outcome (13-item index)

	Informed Consent Tool	Comparison Group
Full sample (n = 89)	74.4	75.1
Higher IQ subsample (n = 46) Median IQ of Higher IQ group = 50	96.6*	87.1

Linear Regression: β (95% CI) = 0.28 (0.01, 0.55)*

*p < 0.05

Study Publications

JMIR RESEARCH PROTOCOLS Furberg et al

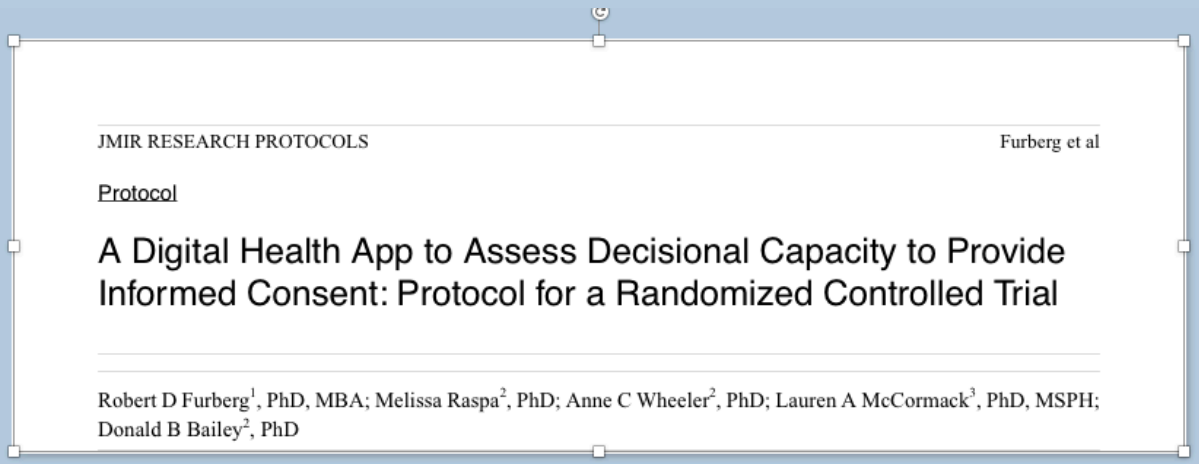
Original Paper

A Digital Decision Support Tool to Enhance Decisional Capacity for Clinical Trial Consent: Design and Development

Robert D Furberg[1], MBA, PhD; Alexa M Ortiz[1], RN, MSN; Rebecca R Moultrie[2], AA; Melissa Raspa[3], PhD; Anne C Wheeler[3], PhD; Lauren A McCormack[4], MSPH, PhD; Donald B Bailey Jr[3], PhD

Furberg, R.D., Ortiz, A.M., Moultrie, R.R., Raspa, M., Wheeler, A.C., McCormack, L.A., & Bailey, D.J. (2018). A digital decision support tool to enhance decisional capacity for clinical trial consent: design and development. *JMIR Research Protocols, 7*(6), e10525.

Furberg, R.D., Raspa, M., Wheeler, A.C., McCormack, L.A., & Bailey, D.B. (2018). A digital health app to assess decisional capacity to provide informed consent: protocol for a randomized controlled trial. *JMIR Research Protocols, 7*(11), e10360.



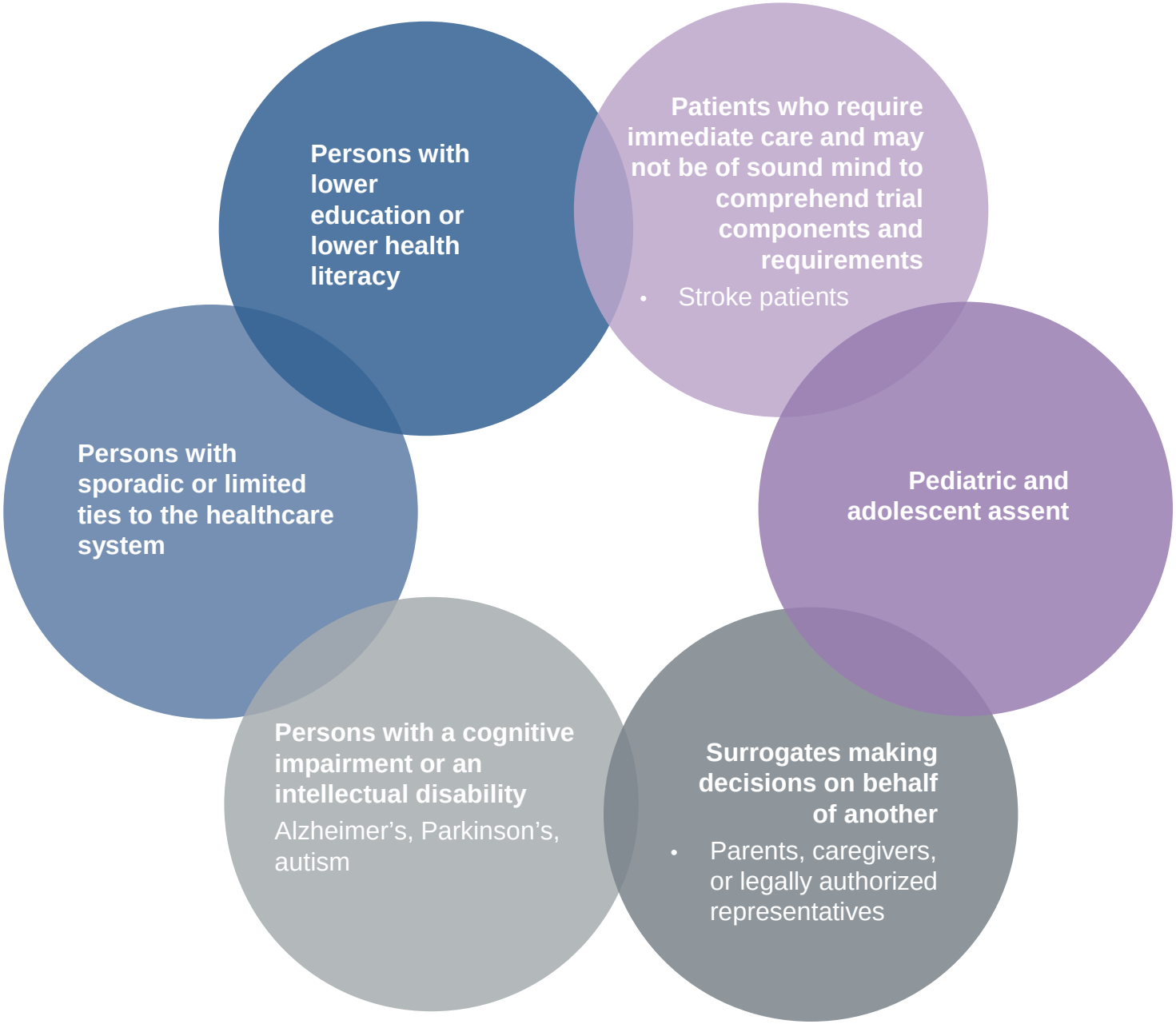
JMIR RESEARCH PROTOCOLS Furberg et al

Protocol

A Digital Health App to Assess Decisional Capacity to Provide Informed Consent: Protocol for a Randomized Controlled Trial

Robert D Furberg[1], PhD, MBA; Melissa Raspa[2], PhD; Anne C Wheeler[2], PhD; Lauren A McCormack[3], PhD, MSPH; Donald B Bailey[2], PhD

Other Populations that May Benefit from Decision Support



Strategies for Infusing Health Literacy Throughout the Clinical Trial Process

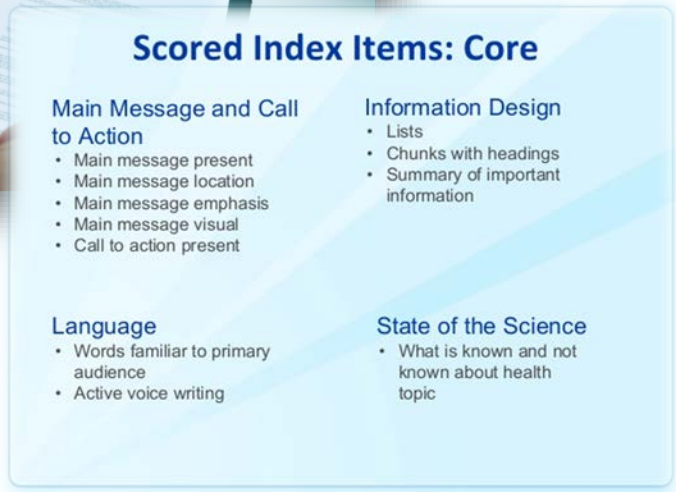
Research Coordinator Training

- Role-playing exercises
- FAQs to anticipate and respond to patient questions
- Take-home materials for patients

Informed Consent Form Development

- Common Rule alignment
- Iterative assessment and revision using evidence-based criteria
  - CDC Clear Communication Index
    https://www.cdc.gov/ccindex/index.html

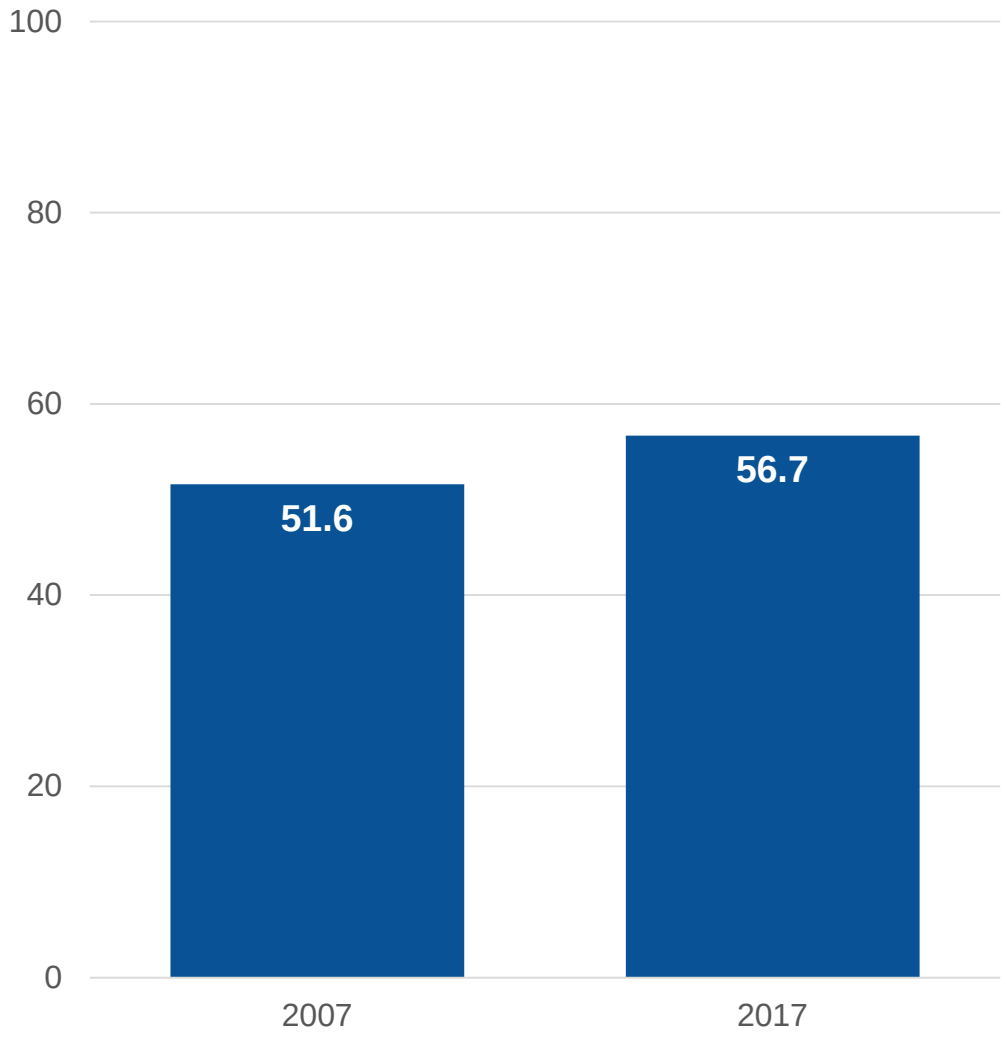
(Baur & Prue, 2014)



Healthy People

"While clinicians are the authorities on the medical evidence, patients are the experts in themselves."

Percent of people who said their health care provider always involves them in their health care decisions as much as they wanted.



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To Learn More…

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Robert Wood Johnson Foundation

CORE
Connected and Open Research Ethics

Network

- IRB, researchers, study participants, students, technologists

Q&A Forum

- Post questions or share expertise by responding to a post

Resource Library

- Share policy and give or borrow IRB-approved research protocol and consent language