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.
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

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

Virtual Clinical Trials: Challenges and Opportunities – A Workshop
November 28, 2018; Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine

Clinical Trial Innovation Summit: Patient-Centric Approaches to Data-Driven Clinical Trials
May 13-15, 2019; Cambridge Healthtech Institute
https://www.clinicaltrialsummit.com/

Drug Information Association (DIA) Global Annual Meeting
June 23-27, 2019

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
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?

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)

<table>
<thead>
<tr>
<th></th>
<th>Informed Consent Tool</th>
<th>Comparison Group</th>
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</thead>
<tbody>
<tr>
<td><strong>Full sample (n = 89)</strong></td>
<td>74.4</td>
<td>75.1</td>
</tr>
<tr>
<td><strong>Higher IQ subsample (n = 46)</strong></td>
<td>96.6*</td>
<td>87.1</td>
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<tr>
<td>Median IQ of Higher IQ group = 50</td>
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Linear Regression: $\beta$ (95% CI) = 0.28 (0.01, 0.55)*

*p < 0.05

Other Populations that May Benefit from Decision Support

- Patients who require immediate care and may not be of sound mind to comprehend trial components and requirements
  - Stroke patients

- Pediatric and adolescent assent

- Surrogates making decisions on behalf of another
  - Parents, caregivers, or legally authorized representatives

- Persons with lower education or lower health literacy

- Persons with sporadic or limited ties to the healthcare system

- Persons with a cognitive impairment or an intellectual disability
  - Alzheimer’s, Parkinson’s, autism
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)
“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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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