MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Inclusion of People with Disabilities in Clinical Research: The Accessibility by Design (ABD) in Clinical Research Toolkit

AbD Toolkit Release Webinar

May 4th, 2023

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- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org) as well as by grants.
- We have no personal conflicts of interest with this presentation.

The MRCT Center and our work in Diversity, Equity and Inclusion (DEI)

The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues [across all stages of] global clinical trials and to create and implement ethical, actionable, and practical solutions.

The MRCT Center, contd.

https://mrctcenter.org

https://mrctcenter.org/2022-impact-report/

MRCT Center DEI Guidance Document and Toolkit

Diversity, Inclusion, and Equity in Clinical Research Guidance Document and Toolkit launched in 2020.

https://mrctcenter.org/diversity-in-clinical-research/

Study Design, Conduct and Implementation

(Corresponding guidance, p. 193-250)

Study Design Logic Model
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Study Design Key Performance Indicators
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Screen Failure Tracking Log
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Eligibility and Enrollment Log
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Site Selection Logic Model
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Site Selection Key Performance Indicators
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MRCT Center Specific Work on Inclusion of People with Disabilities in Clinical Research

Comment

https://doi.org/10.1038/s41591-022-0

Supported decision-making can advance clinical research participation for people with disabilities

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Clinical research often excludes people with disabilities who have impaired decisional capacity, but they can be included through supported decision-making, where their decisions can be assisted by designated supporters of their choosing. This will promote equitable access to research.

People with disabilities who have impaired decision-making capacity are often excluded from participation in clinical research[1]. The research community, including investigators, sponsors and institutional review

Health Affairs

COVID-19 Topics Journal Forefront Podcasts

RESEARCH ARTICLE | DISABILITY

HEALTH AFFAIRS > VOL. 41, NO. 10: DISABILITY & HEALTH

Excluding People With Disabilities From Clinical Research: Eligibility Criteria Lack Clarity And Justification

Disability & Health

VIRTUAL SYMPOSIUM

https://www.nature.com/articles/s41591-022-02035-3

https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00520

The Accessibility by Design (AbD) in Clinical Research Toolkit

The Accessibility by Design (AbD) Toolkit: Background

- 1 billion people (240 million children) globally, and 1 in 4 US adults with a disability. Yet, people with disabilities are often excluded from clinical trials.
- Product safety and efficacy, and the generalizability of study results, are dependent upon the inclusion of the populations who will use the product.
- FDA requires the submission of diversity actions that are focused on race and ethnicity. However, the guidance requests considerations beyond race and ethnicity, such as the inclusion of people with disabilities. Proposed Rule 1557 of the Affordable Care Act (ACA) prohibits discrimination in access to health care for people with disabilities.

The Accessibility by Design (AbD) Toolkit: Overview

- **Purpose:** Some resources for accessibility are publicly available, but they are often limited to one specific topic (e.g., web design). Few resources are specific to clinical research.
- **Audience:** Sponsors, CROs, IRBs, academic research centers, investigators and their research teams.
- **Goal:** "One-stop shop" for accessibility resources to use in the planning, conduct, and communication of clinical research.
- **Format:** Document/PDF
- **Process:** Two rounds of review with disability rights leaders, researchers, nurses, people with disabilities, and family caregivers.

The AbD Toolkit: Overview, contd.

- Focused on clinical research, although many aspects are also applicable to clinical care.
- Generally applicable for supporting inclusion of people with different disabilities, with the exception of people who lack decisional capacity.
- Does not include specification for pediatric participants.
- Does not include specification for disability data collection standards, the different steps necessary for physicians to decide when and how to do a capacity assessment, or description of what “reasonable accommodations” may be when sites have widely varying levels of resources.

The AbD Toolkit: Themes

- Preparing for AbD : General Considerations
- Implementing AbD: Communication Accessibility
- Implementing AbD: Physical Accessibility
- Innovating AbD: Newer Strategies for Inclusion
- Upholding AbD: Accountability and Advocacy

The AbD Toolkit: Key Points

Key points:

- Example at right → Implementing AbD: Communication Accessibility
- Goals coded by skill & feasibility:
  - Green circle (●) "easy"
  - Blue square (■) "moderate
  - Black diamond (◆) "advanced"
- Links to complementary trainings, tools, and resources.

1. Be respectful 	● Don't assume: Ask, and practice active listening.[53] Provide the opportunity for participants to take time to think and to ask for something to be repeated, rephrased, or expressed visually. ● Respect autonomy, treat people with disabilities as capable adults, and speak directly to the individual (e.g., not to a family caregiver or supporter). When possible, keep your face and mouth visible. Treat physical aids as an individual's personal space. Do not pet or walk beside service animals.[54, 55] ■ Ask the participant how they would prefer to be addressed (e.g., person-first language, identity-first language)(see Tool B.I.i). Use plain ["every day" or easy-read] language.[56, 57] Use clear sentences, break down ideas, ask questions one at a time, and avoid medical jargon and acronyms.[58] ■ Provide a quiet and relaxing environment. Avoid cell phones, computers, and ambient office noise and smells while communicating with the participant.
2. Format communication materials for inclusive reading and mental processing 	● Use appropriate font such as large print (minimum of 12-point; 16-point if possible) sans serif font (e.g., Ariel, Calibri, Helvetica, Verdana). Avoid justified text, use of *italics,* and ALL CAPS for emphasis. [59, 60, 61, 62] ● Use icons or graphics to [clearly and concretely] illustrate text. If you include graphics that are not simply illustrative of text, such as data charts or decorative art, insert Alt-text or aria labels for them.[63, 64] Alt-text and aria labels are written statements used to describe a graphic for a person who is not able to see it. Do not use graphics that require abstract thinking. ■ Use contrasting colors[65, 66] and color-blind-friendly palettes.[67, 68] Make key points and clickable items large and separated by white space. ■ Refrain from animation (unless a 'fade in'), visuals that include flashing or spinning, pop-ups or auto-play audio (or allow for those setting options),[69]

The AbD Toolkit: Tools

Tools:

Example at right →

Tool A.II.i: Planning inclusive eligibility criteria to reduce inappropriate exclusion of people with disabilities

Problematic	Preferred
Subject is judged by (or is in the opinion of) the Investigator inappropriate for the study.	Subject is documented by the Investigator to be inappropriate for the study due to the following specific scientific, safety, or ethical reasons: [Specify] (e.g., subject has a cochlear implant and can't complete the necessary MRI for safety reasons).
Subject has any condition that confounds the ability to interpret data from the study.	Subject has a physical or mental condition, as predetermined by the study team, that is expected to significantly impact study data interpretation: [Specify] Predetermination of significant impact is due to the following specific scientific reasons: [Specify] (e.g., subject has a condition documented to be associated with atypical enzyme [X] function).
Participant lacks capacity to consent for themselves.	Participant lacks the cognitive capacity to consent for themselves, as determined [when capacity is questionable] by a capacity assessment conducted with a supporter and any other accommodations desired by the participant.
Participant has any disability that may prevent them from completing all study requirements (e.g., blindness or deafness that is not appropriate for	Participant has any disability that, after accessible study design and accommodations, would prevent them from completing study components

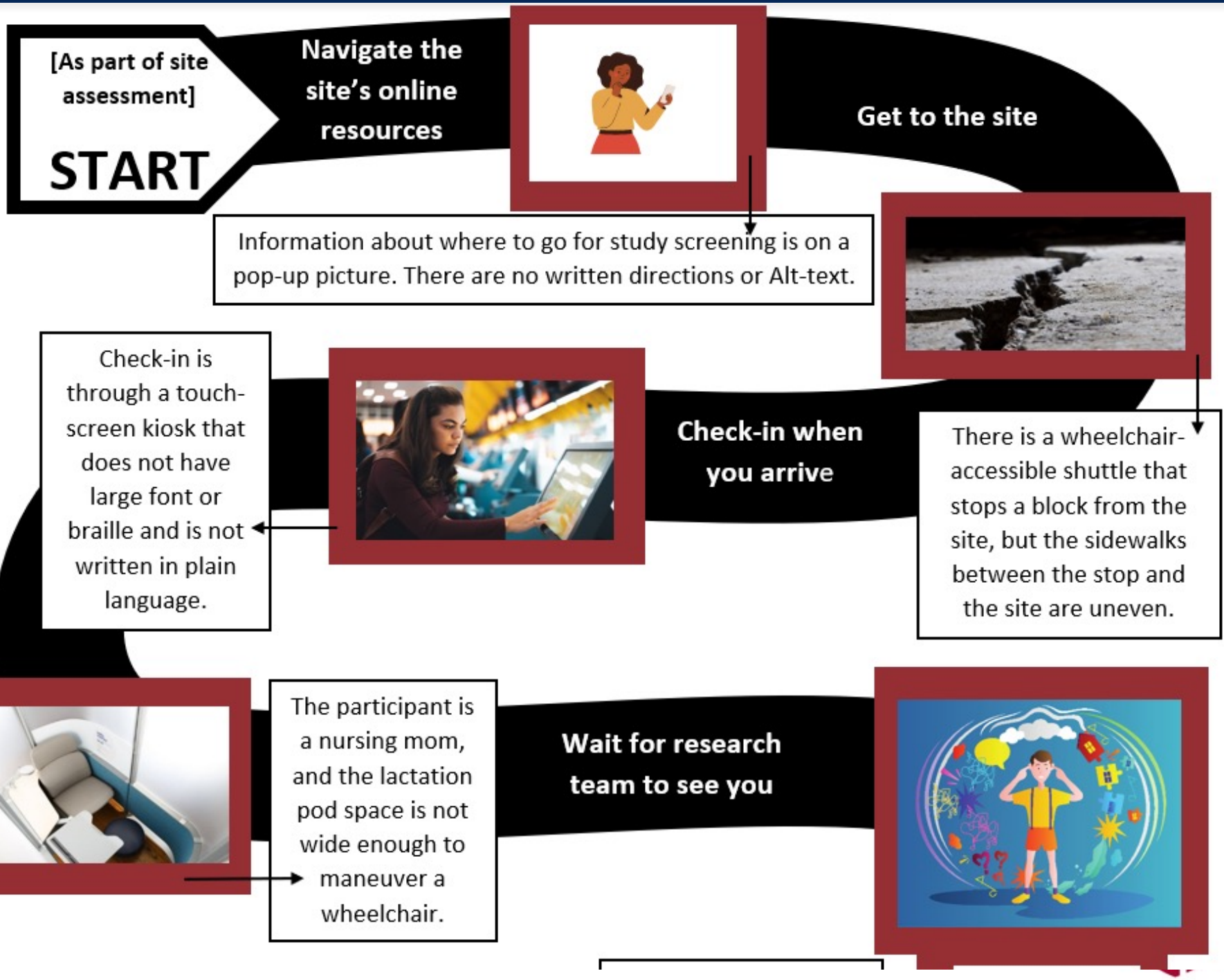
The AbD Toolkit: Tools contd.

Tools:

Example at right ➔

Tool C.I.ii. Map of example challenges in the participant journeys of people with disabilities.

*Note: Use in combination with Tool C.I.i. Site assessment of limitations for inclusion of people with disabilities



The AbD Toolkit: Tools contd.

Tools:

Example at right

Tool D.I: Information brief for individuals asked to act as supporters for supported decision-making

Q: When Are There Decision Points During the Trial?

Clinical trials take place over several stages. These stages include letting people know about the trial, screening, the informed consent process, study visits, the end of the trial, and any follow-up.

- The participant may need support to learn about the trial and to decide if they are interested.
- The participant may also need support during the **informed consent process**. This is when the research team will explain about what will happen during the trial. They will also explain about the participant's rights and tasks. The supporter can assist the participant in asking questions and weighing their options. The supporter can then help tell the research team whether the participant has decided to join or not to join the trial.
- A participant can also decide at any time that they do not want to stay in the trial. They will need to see how they feel at each new step.

Q: CAN I ASK OTHER QUESTIONS? Of course! Here are some examples:

Will I be reimbursed for expenses?

How do you protect my privacy?

Do you provide childcare?

The AbD Toolkit Website

AbD toolkit website: https://mrctcenter.org/diversity-in-clinical-research/tools/**abd_toolkit/**

Panelists

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Questions, Comments, Suggestions

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Acknowledgements

MRCT Center:
Dr. Barbara E. Bierer
Dr. Willyanne DeCormier Plosky
Juliette Pluviose-Philip

Inclusion of people with disabilities in clinical research working group:
Leslie P. Francis, Univ. of Utah Law School
Ari Ne'eman, Harvard University
Dr. Benjamin C. Silverman, Mass General Brigham
Michael Ashley Stein, Harvard Law School
Dr. David H. Strauss, Columbia Medical Center

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