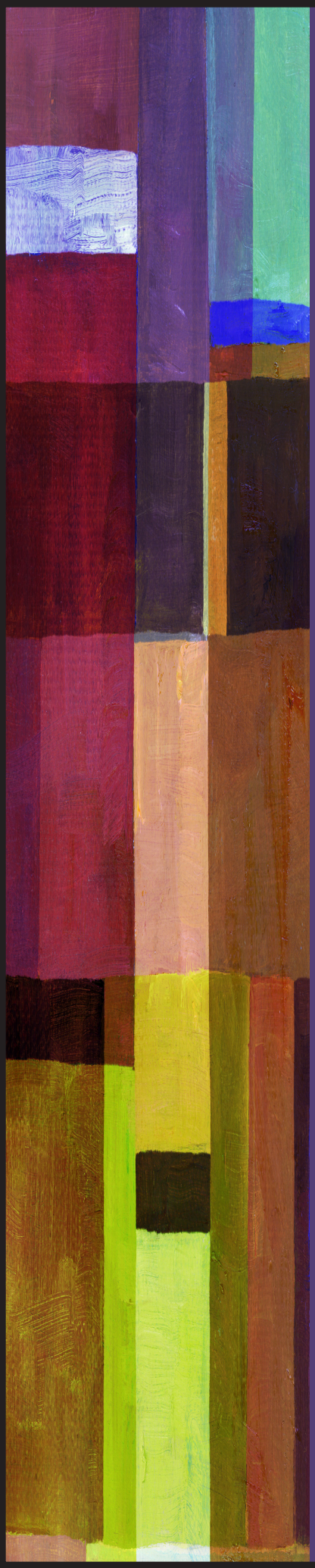

Accessibility by Design (AbD)

A Toolkit for Inclusion of People with Disablities in Clinical Research

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Introduction

Globally there are over one billion people, including 240 million children, with a disability.[1, 2] The more than 61 million people in the US with disabilities make up the largest minority group the nation.[3] Yet, clinical trials often do not include people with disabilities.[4, 5, 6] This is despite numerous international, federal, and state conventions and regulations that protect the rights of people with disabilities and compel non-discrimination. On occasion, the exclusion is based on scientific or safety considerations.[7] However, exclusion can also occur due to unfounded presumptions, researchers' concerns about placing an additional burden on people with disabilities, variability in the study population impacting the results,[8] or insufficient knowledge and resources to support accommodations.

The safety, efficacy, and value of tested products for people with different disabilities can only be known when those products are the subject of study. In addition, diversity in clinical trials can increase the generalizability and impact of study results. Further, disability-inclusive companies have been demonstrated to have higher revenue, economic profit margins, and consumer favorability.[9] This is because working to make products (and trials) accessible accelerates innovation and usability that benefits all people regardless of whether they are someone with a disability.[10] Thus, there are multiple reasons for the clinical research community to act affirmatively to anticipate, identify, and accommodate the needs of individuals with disabilities. Here we provide resources to support members of the clinical research community in their efforts to involve individuals with a variety of disabilities in clinical research, thereby further addressing a commitment to diversity, equity, and inclusion

The *Accessibility by Design (AbD) Toolkit* is meant to complement existing accessibility toolkits [11, 12] that focus not on clinical research but on daily living and healthcare. The AbD Toolkit grew out of the MRCT Center's work on Diversity, Equity, and Inclusion in Clinical Research[13] and aligns with the MRCT Center's *Equity by Design in Clinical Research Metrics Framework*.[14] It is intended to be used by those involved in the design or conduct of clinical research: sponsors, institutions, investigators and research staff, ethics committees/IRBs, research participants, family caregivers, supporters, allies, and patient advocacy groups, among others.

The toolkit is divided into five (5) themes:

- A. Planning for AbD: General Considerations,
- B. Implementing AbD: Communication Accessibility,
- C. Implementing AbD: Physical Accessibility,
- D. Innovating AbD: Newer Strategies for Inclusion,
- E. Upholding AbD: Accountability and Advocacy

Each theme is reflected in the two parts of the toolkit:

- Part 1 provides key points to consider by theme, generally listing "what" should be done. They are organized by categories on the left side of the page, and by AbD skill level in a maturity model format on the right.
- Part 2 provides associated tools, organized by theme, illustrating examples of "how."

We invite you to explore the key points, tools, and cited resources in totality. Alternatively, you may choose to focus on the themes most pertinent to the nature and maturity of your individual or organizational AbD efforts. This toolkit is a living document and will be improved upon with use and comment. **We welcome feedback, suggestions, additional tools and resources, and concerns** (please email: mrct@bwh.harvard.edu). We look forward to continuing to work together with people with disabilities, their allies, and colleagues involved in clinical research to further the inclusion of people with disabilities in clinical research.

Instructions

The **skill levels** for the key points follow straightforward color/shape designations [used in skiing/adaptive skiing]: green circle (🟢) for easy or more readily achievable, blue square (🟦) for moderate difficulty or potentially needing non-clinical expertise (e.g., legal counsel, technical support) or additional resources (e.g., financial) and black diamond (◆) for more advanced goals. Please note that we do not mean to imply that key points labeled moderate/blue square or advanced/black diamond are less important or less achievable. In many cases, it means some additional initial investment is needed, but once in place, these processes and resources can be readily maintained and drop down to an easier skill level.

We have also included **references** throughout. In cases where the reference is to a tool or training, the reference number is a hyperlink indicated by superscript, blue, bold, and underlined font. Click on the reference [hyperlink] number to go directly to the web version of that tool or training. In cases where the reference refers to the source of information, the reference number is given in superscript plain text. Citations for all references, whether tools or sources of information, can also be found at the end of the document.

Finally, when in the **Table of Contents**, you may jump to any section of the document by holding the CTL button and clicking on the row of your choosing.

Disclaimers

Please note that this toolkit does not address accessibility in clinical research for people who lack decision-making capacity. While surrogate decision-making[1] is an important topic, a separate document would be required to address the ethical considerations, legal guidance, and practical tools adequately. We also do not comprehensively address the decisional and communication capacity assessment processes for people with questionable capacity to consent and refer users to other resources, such as the UK National Institute for Health and Care Research (NIHR) INCLUDE Capacity to Consent Framework[15] and the Consent Support Tool.[16] Here we advocate that capacity should be assessed (not presumed)[6], supported decision-making should be accommodated during the capacity assessment process, and that communication aids should support and not supplant an individual's communication. Our focus here is on the responsibility of clinical research stakeholders to engage people and respect individual autonomy to the greatest extent possible.

Also note that any references, links, and examples included in this document are not intended to represent the position of or imply endorsement by the MRCT Center, Brigham and Women's Hospital, Mass General Brigham, or Harvard University. Reciprocally, entities and companies mentioned in the references, links, and examples do not necessarily endorse the work products of the MRCT Center.

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- V.1.1 published 5/4/23, with minor edits to the MRCT Center email address and to Tool A.2.ii.
- V.1.2 published 5/23/23, with one minor edit to the acknowledgements.

[1] A legally authorized representative (LAR), guardian, or health care proxy is the person who may render the decision on behalf of the patient/participant in surrogate decision-making. We do, however, discuss supported decision-making in this document (see Theme D on Innovating AbD: Newer Strategies for Inclusion).

Acronyms

AbD – Accessibility by Design

ACA – Affordable Care Act

ADA – Americans with Disabilities Act

BMI – Body Mass Index

CAPTCHA and reCAPTCHA – Completely Automated Public Turing Test to tell Computers and Humans Apart (reCAPTCHA is a free CAPTCHA service offered by Google)

CEO – Chief Executive Officer

CRO – Contract Research Organization

CYT-R – Cystic Fibrosis Questionnaire-Revised

DEI – Diversity, Equity, and Inclusion

FDA – U.S. Food and Drug Administration

IRB – Institutional Review Board

HRPP – Human Research Protection Program

HYT – Health Years in Total Framework

LGBTQIA+ – Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, Asexual, 2-Spirit, and More

MRCT Center – Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

NJC- [U.S.] National Joint Committee for the Communication Needs of Persons with Severe Disabilities

OEDIB – [Harvard University] Office for Equity, Diversity, Inclusion, and Belonging

PFL – Person (or People) First Language

QALY – Quality-Adjusted Life Year

QI-Disability – Quality of Life Inventory-Disability

SACHRP – Secretary's Advisory Committee on Human Research Protections, HHS

SEC – Securities and Exchange Commission

UNCRPD – United Nations Convention on the Rights of Persons with Disabilities

Glossary

ACCESSIBILITY: Accessibility is when the needs of people with disabilities are specifically considered, and products, services, and facilities are built or modified so that they can be used by people of all abilities.[17]

ALLY/ALLIES: A person or people who support and advocate for disability rights.

DISABILITY: Please note that definitions of disability vary depending on the source. Here we provide two. The Americans with Disabilities Act defines disability as: "A physical or mental impairment that substantially limits one or more major life activities, a record of such an impairment, or being regarded as having such an impairment."[18] The Washington Group on Disability Statistics, a multi-agency expert group convened by the United Nations Statistical Commission City Group to develop internationally comparable data on disability utilizes the United Nations Conventions on the Rights of Persons with Disability (UNCRPD) definition. The UNCRPD defines persons with disability as people with "long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others."[19, 20]

FAMILY [OR INFORMAL] CAREGIVER/S: A family member or friend who provides help, such as assistance with daily life activities, to a person with a disability. For consistency we will use the term family caregiver throughout this document.[2]

PAID PERSONAL ASSISTANCE SERVICE (PAS) WORKER/S [OR DIRECT SUPPORT PROFESSIONAL/S] : A person who is paid to provide personal assistance services to assist a person with a disability. A person that is paid to provide PAS may be someone working in their own individual capacity, through an organization, or at a care facility. For consistency, we will use the term PAS worker throughout this document.

SERVICE ANIMAL/S: An animal, most often a dog, who has been trained to assist a person with a disability. A service animal may accompany a person with a disability to clinical trial and other appointments.

SUPPORTED DECISION-MAKING: A legally recognized strategy that lets people with disabilities choose supporters to assist them in sorting through information, making decisions, and when necessary, communicating.

[2] Please note, the terms person of choice or family of choice are sometimes used in the disability community to refer to (or encompass) trusted allies, family caregivers, and supporters who have been welcomed by a person with a disability into their support network. In this document we do not use these terms because we are focused on the context of clinical trials and principally the interactions between participants and clinical trial staff. While these interactions may involve family caregivers or supporters, they do not tend to involve people such as disability rights lawyers, community organizers, or religious leaders. Where we refer to broader contexts in the document, such as advocacy and awareness-raising, we include allies in the list of people involved.

SURROGATE (or SUBSTITUTE) DECISION-MAKING: A strategy that lets someone who is legally designated to do so, speak and make decisions for an individual who lacks decision-making capacity.

SUPPORTER/S: **In this document** we are using the term supporter/s specifically to mean the person or people that individuals choose to assist them with supported decision-making.

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Part 1: Key Points

Accessibility by Design Key Points Summary

General Considerations

- ☐ Involve people with disabilities in all aspects of research
- ☐ Understand legal and professional responsibilities
- ☐ Plan and budget for accommodations
- ☐ Document how people with disabilities are included and maintain confidentiality
- ☐ Commit to learning from and with people with disabilities

Communication Accessibility

- ☐ Be respectful
- ☐ Format communication materials for inclusive reading and mental processing
- ☐ Design for clarity and consistency
- ☐ Provide/allow for communication aids
- ☐ Test formatting and design

Physical Accessibility

- ☐ Consider the needs of people with disabilities and the people and service animals that may accompany them
- ☐ Map the journey to, around, and from clinical care and research sites
- ☐ Ensure spaces and equipment are accessible
- ☐ Provide or allow for aids
- ☐ When planning for post-trial access to drugs, therapies, or devices, plan to continue accommodations needed by people with disabilities

Newer Strategies for Inclusion

- ☐ Review any relevant regulations or guidance to the strategy
- ☐ Consider the scope for the strategy at your institution
- ☐ Think through process details for the strategy
- ☐ Develop policies and procedures to implement the strategy
- ☐ Create or share resources for participants and family caregivers or supporters involved with the strategy

Accountability and Advocacy

- ☐ Clarify the population size
- ☐ Emphasize regulation, guidance, and diversity planning stipulations
- ☐ Advocate for “Nothing for us without us” in clinical research
- ☐ Highlight the value proposition of inclusion
- ☐ Analyze data, goals, and responsibilities
- ☐ Nurture networks, forums, and policy change

A. Planning for AbD in Clinical Research: General Considerations

Any commitment to AbD in clinical research requires planning and preparation for implementation. The key points below should be considered throughout the trial process and applied to all aspects of service delivery (e.g., communication and physical accessibility) for supporting people with varied disabilities.

AbD Skill level Key: ● = easy; ■ = moderate; ◆ = advanced. Hyperlinked resources in blue underline.

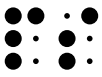
1. Involve people with disabilities in all aspects of research 	● Engage people with disabilities, family caregivers, allies, and their communities as partners, researchers, IRB members, project or study advisors, reviewers, communication designers, co-authors,[21] and/or patient/peer navigators.[22, 23, 24, 25] ■ Appoint people with disabilities to hiring committees.[26] ■ Support the recruitment, hiring, and funding of researchers with disabilities. ■ Support employee and family caregiver resource groups.
2. Understand legal and professional responsibilities 	● Determine who at your institution is responsible for legal advice on clinical research and disability rights. Access institutional guidance on the inclusion of people with disabilities through Legal and Human Resource departments, IRBs, HRPPs, and other offices. ■ Take training on disability rights,[27, 28] diversity,[14] good clinical practice,[29, 30] research regulations, the consent process with people with disabilities, anti-ableism, and allyship.[31, 32] Where possible**,** look for training led by local organizations of people with disabilities. ■ Review the UN Convention on the Rights of Persons with Disabilities (UNCRPD),[20] National Joint Committee for the Communication Needs of Persons with Severe Disabilities (NJC) Communication Bill of Rights,[33] Americans with Disabilities Act (ADA),[34] Section 504 of the Rehabilitation Act,[35] Protection of Human Subjects, 45 C.F.R. § 46,[36] the Secretary's Advisory Committee on Human Research Protections (SACHRP)[37] and others at the international, national, state, and institutional levels.[38]
3. Plan and budget for accommodations 	■ In collaboration with people with disabilities, family caregivers, and allies, allow extra time for sponsors, sites, research teams, and IRBs to design/conduct the study, assess sites for accessibility, identify resources to accommodate people with disabilities, and review the study protocol and participant-facing materials. ■ Allow extra time for each step of study conduct (recruitment, screening, informed consent, study visits, and study follow-up).

	■ Assign staff (trained as aforementioned in key point section 2 above) to lead and advise on the responsibility for the inclusion of people with disabilities shared by all clinical research stakeholders. ■ Inquire about potential participant needs and proactively plan for needed accommodation(s) for each step in the clinical trial process for each participant, respecting the nature of their disability. Plan to allow extra time for participants to complete tasks. ■ For all communications, study products, and equipment, consider the distinct needs of participants with disabilities, family caregivers, and supporters at the site and home. For example, accessing instructions, completing diaries, administration of medication in the appropriate formulation, and engaging and educating support networks. ■ Consider economic accessibility for all people. For example, a well-designed web portal would not be accessible if a participant does not have a computer, smartphone, or access to the internet. Recognize that people with disabilities are more often living in settings of economic disadvantage than people without disabilities.[39] ■ Offer multiple formats for participants to access trial communications (e.g., email, text, phone) at each stage of the trial process, multiple formats for study visits (e.g., telehealth visits, video conferencing, mobile units), and multiple or alternative formats for endpoint measurement. ◆ For participants, family caregivers, and supporters plan to reimburse out-of-pocket costs (e.g., transportation, and accessible transportation if needed) and compensate for time and burden. Check if compensation will impact participants' state or federal benefits and talk with the individual about potential impacts.[40, 41] ◆ Fund modifications, accommodations, and accessibility design testing. Ensure vendor compliance for product accessibility. The latter may refer to accessibility riders in contracts that state the vendor will comply with the institution's accessibility standards, or, for web-based content, will complete a Voluntary Product Assessment Template.[42, 43]
4. Document how people with disabilities are included and	● Encourage formal assessments of protocol eligibility criteria to make sure that they only exclude individuals with disabilities if scientifically or ethically justified. Require clear documentation of justification(s) for exclusion.

maintain confidentiality 	● In the study protocol, recruitment, and informed consent documents, describe modifications and accommodations that will be provided, considered, and/or permissible. Modifications and/or accommodations that are impermissible should be justified based on scientific or ethical reasons. ■ Protect the confidentiality and privacy of people with disabilities in communication with family caregivers, paid personal assistance Service (PAS) workers, or supporters, and in data collection, transfer, storage. ◆ In addition to age, race, sex, gender identity, and other common demographic variables, develop data collection templates that include standardized questions on disability and reporting variables. The proportion of people with disabilities who are screened, enrolled, completed the study, and lost to follow-up requires data collection.[44, 45, 46, 47, 48]
5. Commit to learning from and with people with disabilities 	● Appreciate that relationships are reciprocal: study participants, family caregivers, and supporters are also making adaptations and adjustments for you. ● Get to know people with disabilities and allies to better understand their perspectives (and yours). Include people with disabilities as researchers and guest speakers, work with organizations led by people with disabilities (e.g., Self-Advocates Becoming Empowered,[49] Self-Advocacy Organization of New York,[50] or many other organizations[51]), or check-out a podcast,[52, 53] book,[54] or artistic project by people with disabilities.[55, 56] ● Find, connect with, and obtain advice from local organizations of and for people with disabilities. Understand their capacities and services.

B. Implementing AbD in Clinical Research: Communication Accessibility

Implementation of AbD in clinical research is divided into two parts: communication and physical accessibility. While differences exist in the kinds of communication accommodations desired by people with specific disabilities, there are many commonalities to appreciate.

1. Be respectful 	● Don't assume: Ask, and practice active listening.[57] Provide the opportunity for participants to take time to think and to ask for something to be repeated, rephrased, or expressed visually. ● People with disabilities are capable adults. Respect autonomy 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.[58, 59] ● 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"/easy-read] language [60, 61] and clear sentences. Break down ideas and ask questions one at a time. Avoid jargon and acronyms.[62] ● 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. [63, 64, 65, 66] ● Use icons or graphics (that do not require abstract thinking) to illustrate text clearly and concretely. If including graphics that are not simply illustrative of text (e.g., data charts or art) insert Alt-text for them.[67] Alt-text are written statements used to describe a graphic for a person who is not able to see it. ■ Use contrasting colors [68, 69] and use available tools to check that the degree of contrast is sufficient. Use color-blind-friendly palettes.[70, 71] Make key points and clickable items large and separated by white space. ■ Refrain from animation, visuals that include flashing or spinning, pop-ups or auto-play audio (or allow for those setting options) that are visually disorienting.[72] Refrain from CAPTCHA (e.g., distorted letters) or RECAPTCHA (e.g., image grids) tests that can be blurry and mentally difficult to decipher. ■ Program an option to switch to dark mode to view so that users can view the screen on a black (instead of white) background.[73]

	◆ Use Braille when expecting participants who are blind and upon request. ◆ Limit memorization through use of guest checkout (instead of password-only), biometric "passwords"/signatures, and labels above data entry fields (as labels in those fields will disappear upon data entry). Do not use timeouts.
3. Design for clarity and consistency 	● Provide consistent labeling, terminology, and headers.[74] Define terminology and any unusual words. ■ Supply instructions, reminders, and opportunity for easy error correction.[75] ◆ Use breadcrumbs (e.g. Home > Tools > Accessibility by Design Toolkit), mega menus (i.e. a dropdown menu or expandable navigation area that shows in one place a website's main categories and sub-categories), and highlights in the menu bar (showing the page a user is currently viewing) to map the navigation process and show users where they are.[76, 77, 78]
4. Provide/ allow for communication aids 	● Provide/allow for closed captioning. [79, 80, 81] ■ Provide/allow for in-person assistance, such as live transcription, sign language, tactile/pro-tactile sign language, and supported decision-making. ■ Provide/allow for requested software, such as voice recognition, speech-to-text and text-to speech, vibrational alerts, eye movement tracking, word prediction, keyboard and tab-only programs, and noise reduction. [82, 83, 84] ◆ Provide/allow for requested hardware, such as adaptive electronics (e.g., mouse, keyboard, joysticks, trackballs), adaptive switches (e.g., mouth stylus, sip and puff, head/foot/eye-blink switches), and communication devices (e.g., screen readers, touchpads).
5. Test formatting and design 	● Run accessibility, plain language, and health literacy checkers.[85, 86, 87] ■ Check that the home/first page and each internal page on a website, paper-based survey, form, or information packet is readable- both in English and in any translated languages. For example, some Spanish phrases are longer than English ones. The translated text may then become crowded and overrun any text boxes or graphics that has a pre-set size in the English version. ■ Check accessibility on different browsers (e.g., Chrome, Firefox, Safari) and device types (e.g., mobile phones, telephones, laptops, desktops, tablets). ◆ Test that help-desks and tech support are accessible and utilized by participants. Please note that such services may be provided by contracted parties that are associated with, but external to, the research team or site.

C. Implementing AbD in Clinical Research: Physical Accessibility

Similar to communication accessibility, while differences exist in accommodations desired by people with specific disabilities (e.g., cognitive, visual, mobility), the following points apply to all. While we generally focus on mobility, sensory aids, environmental conditions here, and communication modalities and aids and in Theme B, we recognize that this disaggregation can be artificial. A person with a physical disability may, for example, also have a hearing disability. Other challenges to inclusion should also be considered, such as, in the US, people whose preferred language is other than English.

1. Consider the needs of people with disabilities and the people and service animals that may accompany them 	● Discuss with people with disabilities, family caregivers, and supporters their priorities for assistance:[88] types of physical spaces, medical equipment, and remote access; special needs for transportation and travel; valet parking; 3rd parties that arrange for travel;[89] childcare/eldercare; respite care;[90] built-in breaks for personal care needs; planning visits around medication and care schedules; support groups; helplines. ● Ask permission before touching a person's mobility aids. Ask permission before petting, or giving water, food, or toys to service animals.[91, 92]
2. Map the journey to, around, and from clinical care and research sites 	● Test the journey to the site, within the site, and returning home (e.g., routes to the site from various points, location of parking; number, type of doors, means of operation, and force needed to open them; check-in procedures, etc.) from multiple disability perspectives and for compliance with ADA guidelines. ● Share information about local mass transit systems and their accessibility options, and about paratransit options outside of mass transit fixed routes (e.g., dial-a-ride, accessible minibuses). Prepare and pay for accessible transport, if needed, to and from the site. ● Plan for lodging that is nearby, accessible, and can accommodate service animals, if needed. ■ Avoid activities that are situated in difficult environmental conditions (e.g., hot pavement, areas where water tends to pool, cobblestone paths). Make sure that ice and snow are cleared and, to the greatest extent possible, not obstructing visibility or mobility. ◆ Address necessary accommodations for navigation around the site, such as sidewalk maintenance, ramps, alternatives to stairs, reduced distance from the site entrance to the visit office, automated doors, door push buttons, touchless switches, clear signage, and availability of people to provide directions/assistance.

3. Ensure spaces and equipment are accessible 	● Assess whether different types of spaces are accessible (bathrooms and bathroom stalls/doors, waiting/changing/exam/conference rooms, diagnostic and lab spaces and equipment, breastfeeding pods, playgrounds, and recreation spaces).[93] Note that there is a new app called Ahoi that works a bit like the Waze driving app. Ahoi "lets users input their own needs and returns personalized scores for accessibility of different places," based on crowdsourced accessibility reports generated by users.[94] ■ Think about a person's comfort and positioning for procedures and tests. Train staff to assist with mobility and transfers safely (e.g., assisting a person into an MRI machine), and if needed or requested by the individual, allow the family caregiver or paid PAS worker to assist. Address challenging aspects of these spaces (size, ledges/stairs, obstacles, noise, lighting, crowding, odors, privacy). ◆ Ensure the availability of medical, diagnostic and office equipment that can accommodate people with disabilities (e.g., adjustable-height tables, scales that fit wheelchairs, emergency buttons within easy reach, sliding boards for transfers).
4. Provide or allow for aids 	● Provide or allow for requested mobility aids such as canes, standing/knee walkers, scooters, or wheelchairs. ● Provide or allow for sensory aids such as chewy tools, sensory swings/chairs, noise-canceling headphones, and weighted blankets.
5. When planning for post-trial access to drugs, therapies, or devices, plan to continue accommodations needed by people with disabilities 	■ Consider local contexts, and whether the health system can provide accommodations needed by trial participants with disabilities if planning to transition participants from the investigational product to other appropriate care. ◆ Provide the continuation of associated medical care, infrastructure, and accommodations necessary, if offering post-trial product use. ◆ Ensure maintenance of implanted or prosthetic devices.

D. Innovating AbD in Clinical Research: Newer Strategies for Inclusion

As newer strategies (i.e. [policy] modifications or [individual] accommodations) for inclusion are requested, tested, and refined, clinical research stakeholders must be prepared to adapt and advance their service delivery accordingly. While there may be some strategies that clinical research stakeholders are familiar with, there are others that may be "newer" to them because the technology or concept is new, they are not familiar with the modification or accommodation, or guidance has not yet been developed to support the strategies. Please note: We use the example of supported decision-making in the key points below and associated Theme D tools to illustrate considerations and practices concretely for supporting newer strategies for inclusion requested by people with disabilities.

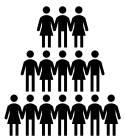
1. Review any relevant regulation or guidance to the strategy 	■ International: United Nations Convention of the Rights of Persons with Disabilities (UNCRPD)[20] and country-specific disability laws. ■ Federal: Americans with Disabilities Act (ADA),[34] Section 504 of the Rehabilitation Act,**Error! Bookmark not defined.** Protection of Human Subjects, 45 C.F.R. § 46;[36] Secretary's Advisory Committee on Human Research Protections (SACHRP),[37] Subcommittee on Inclusion of Individuals with Impaired Decision-making in Research Recommendation 6,[95] Proposed Rule to Section 1557 of the ACA.[96] ■ State: National Resource Center for Supported Decision-Making.[97]
2. Consider the scope for the strategy at your institution 	● Define and acknowledge the limits of the strategy. For the example of supported decision-making, if capacity cannot be improved by 3rd party support to the degree necessary to meet the demands of the consent process [e.g., a person who is acutely delirious, in a coma or without a functional communication system to communicate preferences], supported decision-making would not be appropriate. ● Collate descriptive information and lessons learned about implementation of newer strategies (e.g., supported-decision-making) from other studies and institutions. ■ In collaboration with people with disabilities, consider when the strategy would be utilized for each stage of the trial (e.g., recruitment, screening, capacity and communication assessment, informed consent, study visits and participant tasks, safety reporting, post-trial follow-up). For instance, in supported decision-making, collaborate with people with cognitive and developmental disabilities.

3. Think through process details for the strategy 	■ If newer strategies are recommended, consider the implications for data integrity and comparability and the need for IRB review and approval prior to initiating change. For example, is supported decision-making a modification to the study protocol that needs to be reviewed and approved by the IRB? ■ Consider risks to participant privacy with implementation of a newer strategy, and if there are any applicable state laws. For example, be aware of who may be a supporter under state law and what rights supporters are afforded to access participant medical records. ■ Determine whether an agreement is necessary to provide or allow for the newer strategy in the trial, and if so, the formality level (e.g., legally binding), format (e.g., oral, written), and necessary parties for such an agreement. ◆ If the site will provide access to a newer strategy for people with disabilities who desire it, determine how that strategy will be provisioned. If a piece of equipment, can the equipment be accessed, purchased, and installed by all sites? If, for example, the site provides, upon request, a person to act as a supporter, how the staff would be chosen, trained and/or credentialled should be considered, as well as whether and how the participant-supporter relationship will be sustained. ◆ Determine whether and when assessments of participants will be required to proceed/continue with the newer strategy (e.g., based on study population and procedures), which assessment tools to use, and what training is necessary to conduct assessments with those tools. For supported decision-making, determine the process for assessment of decisional capacity.
4. Develop policies and procedures to implement the strategy. 	● Determine whether any changes in are necessary to adopt or adapt the newer strategy. For instance, in supported decision-making, a change in IRB policy may be required if the institution determines that supporters should be offered an exception is documented and justified. Institutional policies may require that research teams should always ask participants if they would like to be accompanied by a supporter and if they have a supporter who could assist with supported decision-making.

	● New or revised procedures may be needed to accommodate the change. For example, a process to allow for and document supported decision-making during the capacity assessment. ■ Changes in consent procedures may be needed (e.g., to include supported decision-making). ◆ Develop guidelines for when it may be necessary to re-assess the participants (e.g., for decisional capacity), to re-consent, and re-visit family caregiver, paid PAS worker, or supporter arrangements.
5. Create or share resources for participants and family caregivers or supporters involved with the strategy. 	● If the assistance of a family caregiver, paid PAS worker, and/or supporter is necessary to utilize the newer strategy, periodically reassess how both the individual and the person assisting view that the arrangement and whether it is effective for supporting the autonomy of the individual with a disability. ● Discuss with people with disabilities, family caregivers, and supporters if there is additional assistance needed to facilitate using the newer strategy (e.g., transportation, reimbursement). ■ Determine what information is necessary to capture about the newer strategy and share with family caregivers and supporters. ◆ Share resources that may be helpful for participants, family caregivers, and supporters involved in the newer strategy. For supported decision-making these could include health care guides,[98] information about respectful communication with augmentative and alternative communication users,[99] guides and training for understanding supported decision-making.[100, 101]

E. Upholding AbD: Accountability and Advocacy

Commitment is necessary to design, plan, and conduct a trial in a way that supports the inclusion of and accessibility for people with disability. The development, strength, and sustainability of such commitment often requires ongoing advocacy. The key points below list actions and arguments that can be leveraged to strengthen the foundations for a growing community of disability rights allies.

1. Clarify the population size 	● Stress that there are 1 in 4 U.S. adults[3] with a disability. Globally, there are 1 billion people,[1] including 240 million children,[2] with a disability. Most people or their loved ones will experience a disability during their lifetime. ● Communicate that the U.S. Office of Disability Employment Policy categorizes people with disabilities as the third-largest U.S. market segment, after Hispanics and African Americans.[9] The global market for disability-related products is around U.S. $13 trillion.[10] ● Build an understanding that product safety and efficacy, and the generalizability of study results, are dependent upon the inclusion of the populations who will use the product or for whom the product is intended.
2. Emphasize regulation, guidance, and diversity planning stipulations 	■ Underline that international, national, state, and institutional guidance compels non-discrimination of people with disabilities (see Theme A above). ■ Fulfill the U.S. Food and Drug Administration (FDA) requirement that organizations and investigators to submit Race and Ethnicity Diversity Plans and to consider diversity beyond race and ethnicity, inclusive of underrepresented populations such as people with disabilities.[102] ■ Understand that the US Securities and Exchange Commission (SEC) has approved new rules that require companies that list shares on the Nasdaq Stock Market Exchange to disclose the race, ethnicity, and gender profiles for their Boards and to meet targets for diversification. In April 2022, the UK Financial Conduct Authority (FCA) approved similar rules. Although these rules do not specifically reference disability, they do speak to greater corporate accountability for diversity and inclusion.[103, 104, 105] ■ Draw attention to Proposed Rule 1557 of the Affordable Care Act (ACA), which prohibits discrimination in access to health care for people with disabilities and other populations.[106] ◆ [When 1557 is finalized], fulfill the requirement that all health program and activities (including private insurance) that receive federal funding will be required to deliver services in the most integrated setting appropriate to an individual's needs and in the most inclusive manner possible.

3. Advocate for "Nothing for us without us" in clinical research 	● Express that the safety, efficacy, and value of tested products for people with different disabilities cannot be known unless they are the subject of study. ● Note that while not all research offers direct benefit, the benefits of participation in clinical research can include access to drugs, therapies, and devices not otherwise available in addition to the opportunity to possibly help others. Describe how the exclusion of people with disabilities from the opportunity to participate, without appropriate justification, is discriminatory. ● Convey that the population of research participants should reflect those affected by the condition and those for whom the product is intended. A lack of diversity in clinical trials reduces the generalizability and impact of study results. ● Explain that some clinical trials are designed to understand, treat, or ameliorate the condition giving rise to the disability. However, people with disabilities also suffer from other prevalent health conditions that are frequently studied in clinical research; those who use a wheelchair, for example, may also have cancer,[107, 108] and people with Down Syndrome are likely to develop early-onset Alzheimer's Disease.[109]
4. Highlight the value proposition of inclusion 	● Advocate that disability-inclusive companies are documented to have achieved 28% higher revenue, double the net income, and 30% higher economic profit margins. [9] ● Show examples of how disability-inclusive companies have more innovative products and services produced by and for people with disabilities (e.g., cruise control, phone texting, the internet). [10] Working on accommodations for people with disabilities not only accelerates innovation but can also benefit all people regardless of whether they have a disability. ● Point out that 92% of consumers view companies hiring people with disabilities favorably.[110] ■ Describe how people with disabilities have been shown to have higher employment retention rates and efficiency (e.g., in one company assistive devices and keyboard shortcuts allowed visually impaired telemarketers to make 100% more dials than their non-disabled peers).[111, 112]

5. Analyze data, goals, and responsibilities 	■ Set up opportunities for people with disabilities, allies, and community groups to share feedback on their experiences with the trial/s (e.g., surveys, complaint portals, focus groups) and with any partnerships involving clinical research institutions. Gather lessons learned from research teams. ◆ Determine what measures you will ask about, (e.g., data elements collected) and scripts so that the process of data collection are respectful. Review and analyze data collected on the proportion of people with disabilities who were screened, enrolled, completed the study, and lost to follow-up during the trial/s. Revise metrics if necessary to capture data more accurately on the inclusion of people with disabilities. ◆ Transparently share trial results on the proportion of people with disabilities who were screened, enrolled, completed the study, and lost to follow-up. ◆ Assess trial and [responsible] staff performance for inclusion of people with disabilities, periodically review and revise goals, and determine if processes for strengthening accountability can be improved.
6. Nurture networks, forums, and policy change 	● Recognize, as stated in the AAMC Principles of Trustworthiness that, "The project may be over, but the work is not."[113] Progress toward equity and justice requires continual commitment, engagement, and advocacy. ● Become active within institutional, local, national, or global networks and conferences to develop improved practices, policies, and legislation. ■ Share lessons learned, feedback from participants on accessibility, and plans for improving. Collaborate with participants with disabilities, family caregivers, supporters, and allies in review and authorship of publications. Where possible, include plain language summaries/abstracts in publications. ◆ Advocate for and execute a research agenda that asks challenging questions and informs policy change. For example, some questions currently include: - How can data on inclusion of people with disabilities in clinical research be captured in a standardized way? When is it necessary to and how should one ask personal questions of this type? - Whether and what barriers do research sites and investigators encounter that limit inclusion of people with disabilities in clinical research. - What are reasonable accommodations when sites have widely varying levels of resources? - What are the different steps for physicians to decide when and how to do a capacity assessment? - How would enforcement of ADA in clinical research be accomplished?

Part 2: Tools

Tool A.1: Checklist of procedural and logistical practices to support inclusion of people with disabilities

Description: At each stage of a research study, there are logistical and procedural considerations to help lower the barriers for the inclusion of underrepresented populations. This checklist has been adapted[114] for use when considering the inclusion of people with disabilities in a clinical trial. This list is non-exhaustive and intended to prompt attention to affirmative steps to address DEI with reference to people with disabilities.

Intended audiences: 1) For sponsors to plan, conduct, and report trials, 2) For CROs to plan site engagement strategies. 3) For investigators and their study teams to consider and operationalize; 4) For HRPPs and their IRBs to review and distribute, and 5) For institutional quality assurance/quality improvement (QA/QI) programs to use in monitoring.

Tool A.1: Checklist of procedural and logistical practices to support inclusion of people with disabilities

DIVERSITY, EQUITY, & INCLUSION (DEI) STUDY LEVEL CONSIDERATIONS

Pre-Study Considerations

- ❑ Train all staff in legal and professional responsibilities (inclusive of disability rights), respectful communications, and personal bias.
- ❑ Form and nurture partnerships with disability communities. Engage with community physicians, patients, and companions to inform the study question, design, and conduct.
- ❑ Develop accessible and health-literate communications, visual supports, and educational activities to enhance diverse participant awareness, access, recruitment, and retention.
- ❑ Ensure site/equipment accessibility (e.g., ramps, comfortable bath/changing/waiting rooms).
- ❑ Establish processes to minimize burden at each trial stage (e.g., accommodations, transportation, protocols for paying people with disabilities and companions, flexible appointments, decentralized trial components) as appropriate to reduce burden.
- ❑ Create a standard mechanism to collect, record, and track demographic and non-demographic variables of people with disabilities screened, offered, and consented into study.
- ❑ Develop eligibility criteria that only exclude people with specific disabilities if scientifically justified.
- ❑ Systematically record reasons for screen failure. Periodically evaluate screen failure data.

On-Study Considerations

- ❑ Document the bases of decisions for excluding people with disabilities from a trial and/or not offering/allowing accommodations that would facilitate inclusion.
- ❑ Devise a simple and clear informed consent process for all people that is conducted in a health-literate, culturally- and linguistically-appropriate, and accessible manner.
- ❑ Provide translation services of the informed consent form and other trial processes for all people in their preferred language (including sign language), as applicable.
- ❑ Apply accessibility principles to all English and preferred language study documents and provide/allow for accommodations for people with disabilities.
- ❑ Provide for flexible strategies that enable all people and their companions to adhere to the expectations of the study (e.g., accommodations; adapted monitoring/endpoints, amenable clinic hours and in-person/virtual locations; provision of child/elder/respite care; transportation, lodging, and food assistance; appropriate reimbursement and compensation for participants and companions).
- ❑ Offer regular, respectful, and accessible communication through the platform/s (e.g., phone, email, virtual meetings) and modalities (e.g., Braille, closed-captioned, keyboard-only) preferred by participants, inclusive of people with disabilities and their companions, to foster participant understanding.
- ❑ Establish a monitoring and evaluation system to ensure timely interventions if actual enrollment does not meet expected enrollment or if the actual enrollment does not reflect the expected demographic(s) intended for the study.
- ❑ Monitor retention to study by demographic and non-demographic factors.
- ❑ Put practices in place that provide continuous education, support, and outreach to people with disabilities, their companions, and their communities.

Post Study Considerations

- ❑ Plan for sub-group data analysis, including examination for heterogeneity of treatment effects among people with disabilities.
- ❑ Provide clear and accessible communication around end-of-study expectations, including transitions of care, potential later outreach, and timing of further communications.
- ❑ If the study involved an investigational product and accommodations to utilize the product, anticipate continued access to the investigational product and accommodations to utilize the product for people who are benefitting from the treatment and have no other equivalent options for treatment.
- ❑ Return aggregate and, to the extent possible, individual study results in accessible, health-literate, formats to study participants.
- ❑ Return aggregate results, if applicable, in accessible, culturally- and linguistically-appropriate, formats to the community.
- ❑ Conduct post-study survey of participants, including people with disabilities, to learn what worked well and where to improve.
- ❑ Collate lessons learned. Review performance and accountability. Revise policies to better include people with disabilities.

Tool A.2.i: Planning inclusive eligibility criteria to reduce exclusion of people with disabilities

Description: Study protocol eligibility criteria often use vague language that can be broadly interpreted to exclude people with disabilities.[7] Examples of problematic eligibility criteria (Left), adapted from actual protocols), and preferred versions of those same criteria (Right) are shown below.

Intended audiences: 1) For sponsors, investigators, and study teams to utilize when drafting eligibility criteria, 2) For IRBs and regulatory authorities to consult when reviewing eligibility criteria, and 3) For people with disabilities, family caregivers, and allies to reference.

Problematic	Preferred
Subject is judged by (or is in the opinion of) the Investigator inappropriate for the study.	Participant is documented by the Investigator to be inappropriate for the study due to the following specific scientific, safety, or ethical reasons: [Specify] (e.g., participant has a cochlear implant and cannot complete the required MRI for safety reasons).
Subject has any condition that confounds the ability to interpret data from the study.	Participant has a physical or mental condition, as determined by the study team, that is expected to significantly impact study data interpretation: [Specify] Determination of significant impact is due to the following specific scientific reasons: (e.g., participant is on an immune-suppressive and can't receive live vaccine; has a condition documented to be associated with atypical enzyme function).
Participant lacks capacity to consent for themselves.	Participant lacks the cognitive capacity to consent for themselves, as determined by a capacity assessment conducted with a supporter and other accommodations requested 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 age, severe language difficulty).	Participant has any disability that, after accessible study design and accommodations, would prevent them from completing required study procedures critical for outcome assessment.

Tool A.2.ii: Changes to outcome measures to reduce exclusion of people with disabilities

Description: Outcome measures used in clinical trials should be reviewed for accuracy, reliability, and applicability, including for people with disabilities. Outcome measures should accommodate people with disabilities, and not "discount" the lives and abilities of people with disabilities. For example, if measuring functional strength, an outcome measure of handgrip strength could exclude people who are quadriplegic, while a measure of tongue pressure would not. Body Mass Index as an outcome measure would be inappropriate for people with limb loss or people with restricted height or who have difficulty standing. Alternate outcome measures may be considered for these groups, such as the BMI Calculator for People with Limb Loss[115] and the BMI Arm-Span Model[116] respectively. Health-related Quality of Life Years (QALY) are more appropriately adapted to the Health Years in Total Framework (HYT)[117], the Quality of Life Inventory- Disability (QI Disability)[118] [for children and adolescents with an intellectual disability], or condition-specific measures such as the Cystic Fibrosis Questionnaire-Revised (CFQ-R).[119]

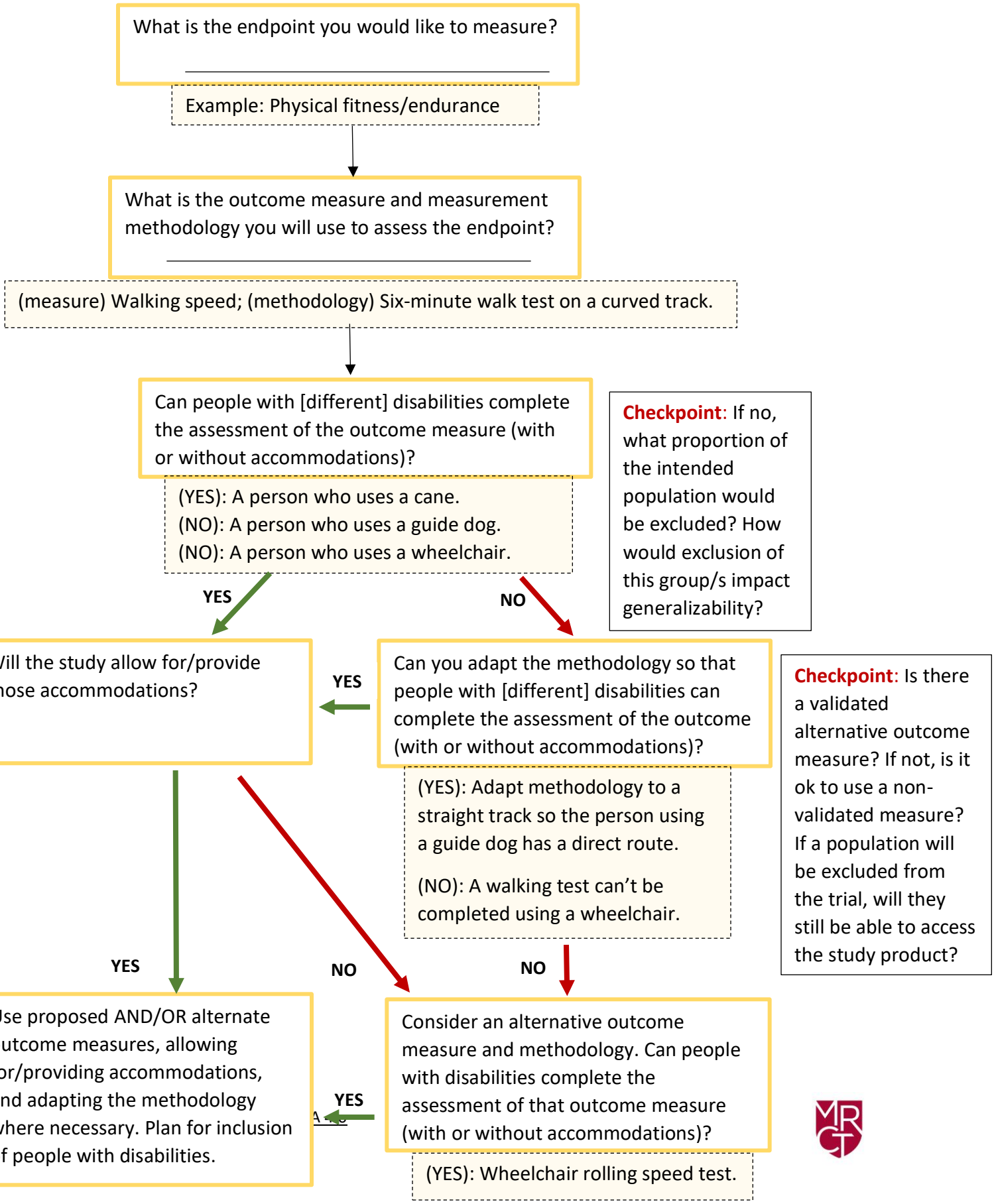
The MRCT Center has created a tool to use in the process of selecting for considering outcome measures to address inclusivity of people with disabilities:

- First, choose the outcome measure for the study question. Please note, if this is a new study, you will need to pick the endpoint[3] you are studying (e.g., physical fitness, lower limb functional mobility) and then choose an outcome measure that is appropriate for the study question.
- Second, consider the methodology/tasks to measure that outcome and whether they could be problematic for people with different disabilities despite providing accommodations.
- Third, consider, consider whether the method could be adapted and validated, if necessary, to measure the outcome. Finally, if people with disabilities would nevertheless be excluded, consider whether a new outcome measure and methodology could be substituted.

Intended audiences: 1) For sponsors, investigators, and study teams to determine the outcome measures used in the study, 2) For HRPPs, IRBs, and regulatory authorities reviewing proposed outcome measures for inclusivity, and 3) For payers and national health authorities conducting value assessments of product safety, efficacy, and effectiveness.

[3] In this tool we use the term endpoint in line with the definitions in the Principles of Clinical Pharmacology (third Edition) and the US NIH National Center for Advancing Translational Sciences (NCATS) Toolkit. These are respectively, "Characteristics that directly measure how a patient feels, functions, or survives, [which] have been traditionally used to evaluate the impact of drug therapy," and "An endpoint is a targeted outcome of a clinical trial that is statistically analyzed to help determine the efficacy and safety of the therapy being studied. Endpoints for a clinical trial may include one or more clinical outcome assessment." See: https://www.sciencedirect.com/topics/medicine-and-dentistry/clinical-endpoint and https://toolkit.ncats.nih.gov/glossary/endpoint/). Others might use the term "construct." Using either term, it is important to note that, depending upon the endpoint, an outcome measure may not be inappropriately excluding people with disabilities. For example, if the endpoint is mobility of the legs, and the outcome measure is walking speed, people who use wheelchairs could participate in the assessment and would score a 0. However, if the endpoint is physical fitness/endurance, and the outcome measure is walking speed, the outcome measure is not appropriate to measure physical fitness for people who use wheelchairs, and another outcome measure should be considered (such as wheelchair rolling speed).

Tool A.2.ii: Changes to outcome measures to reduce exclusion of people with disabilities



Tool A.3: Information brief for people with disabilities participating in clinical research

Description: To inform potential participants about clinical trials, research stakeholders create communication materials that illustrate frequently asked questions and responses.[120, 121, 122] The example below, adapted from the MRCT Center's *What is Clinical Research*,[123] tailors basic questions and responses about clinical research for all audiences. It is written in plain language, specifically mentions research beyond "medicines," inclusion of people with disabilities, and the allowance for or provision of aids and supports for participants.

Intended audiences: 1) For clinical trial stakeholders to post on their websites, 2) For healthcare providers to share with patients when discussing possible participation in clinical trials, 3) For research teams and patient navigators to share with potential participants during the screening and consent processes, 4) For patient advocacy organizations to post and share with their membership, and 5) For participants, family caregivers, supporters, allies, and the public.

What is Clinical Research?

A Guide for People with Disabilities

Clinical research is a way to learn new things about products like drugs, treatments, or vaccines. These products are sometimes made to keep people from getting sick. Other times they are for taking care of people if they don't feel well or need help.

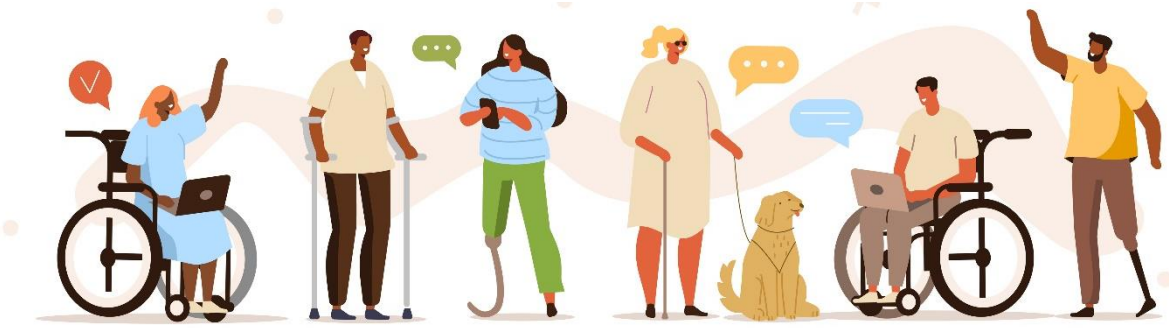
Clinical research can also test new kinds of **aids** and devices. An aid might be something like a small machine that a person wears to hear better. Or it might be something like a robot hand that a person wears to help pick up things.

Q: Who Leads Clinical Research?

- People who lead research are called **investigators**. The person who is the head of the research team is called the Principal Investigator. Doctors, nurses, and scientists can be investigators.
- **Study coordinators** are part of the team. They help plan what happens in a study. Patient navigators are people who set up visits, show you where to go, and get you things you need.
- Special groups called **Institutional Review Boards** (IRBs) look over the plans for clinical research and set the rules to keep people safe.
- Often, the places that make products pay for clinical research on that product.

Q: Why Should I Do Clinical Research?

- Clinical research tests whether drugs, treatments, vaccines, and aids are safe and work for many kinds of people.
- Clinical research may be able to help you. But if research does not work for you, it may still help others now or in the future.



Q: Who Participates in Clinical Research?

- Many people, including people with disabilities! Taking part in research helps investigators learn about which things work for you and people like you.
- People who take part in research are called **participants**, or subjects, but not patients. That is because it is not the job of research to treat your condition.

Q: Can I Use Aids or Supporters?

- Yes! Investigators should ask if there is something that you need and do their best to help you get it. You can ask for special kinds of cars or buses to bring you to and from the place for the research. You could also ask for extra time to do things, or to have a supporter help you decide what you want to do.
- You can bring your own aids such as crutches or screen readers if you want. You can bring one or more people with you to help.
- Sometimes the place where you go for the research will have the aids that you need if you would rather use theirs or can't bring your own.
- You might not be allowed to use aids or supporters in some cases, such as when it is not safe. If so, investigators should explain why. And feel free to ask.

Q: Can I ask other questions? Of course! Here are some examples:

Can I get hurt if I take part in the clinical research?

Do you keep the things I tell you secret?

Have you worked with people like me before?

Tool A.4. Research participant's bill of rights, recreated for people with disabilities

Description: Similar to handouts that illustrate frequently asked questions and responses about clinical research, a participant bill of rights is a fundamental piece of communication. Below, we adapted the *Research Participants' Bill of Rights*[124] to be inclusive of people with disabilities.

Intended audiences: 1) For research teams and patient navigators to share with potential participants during the screening and consent processes, 2) For physicians to share with patients when discussing possibilities for participation in clinical trials, and 3) For sponsors and CROs to post on their websites.

You have the right:

- To be treated in a caring and polite way, including any person that comes with you.
- To ask for, and receive, fair accommodations (e.g., aids or supporters).[125, 126, 127]
- To know what the study is about and why it may or may not be an option for you.
- To know what each page means in the forms, apps, or surveys that you are asked to fill out.
- To know what happens in the study and why it is it is not like what happens when you go to your normal doctor.
- To know about the risks (ways you might feel sick or get hurt) during or after the study.
- To know about the benefits (ways you might feel better or pleased) from being in the study.
- To know about other drug, therapy, or device that are options to consider outside the trial. To know how they might be better or worse for you than the one being studied.
- To know about how the study team would help you if you feel worse, get hurt, or can't do things as well as before.
- To ask questions and take your time when you're deciding if you want to be in the study. To ask questions and take your time when you are working on study tasks.
- To be informed if the study team has learned new things about the risks or benefits of being in the study. To be informed if there are changes to the study.
- To say no to being in the study, either before it starts, or at any time during the study.
- To be given a copy of the approved consent form if you agree to join the study.

Tool B.1.i: Examples of person-first language

Description: Person (or people) first language is a means of communication by which the words used recognize the person first and not their disability. For people who prefer it, person-first language is about respect, dignity, agency, and seeing the person first and the disability second (e.g., person with autism). Please note however, that there is debate about the appropriateness of person-first language. Some people view it as denying the importance of the disability to the individual's lived experience. They prefer identity-first language that puts the disability first in the description (e.g., autistic person), and view identity-first language as an expression of empowerment and positive social identity. Thus, engaging in open conversation, including the use of preferred language and necessary accommodations, allows individuals to express their preferences. Below we provide examples of potentially problematic (Left) and preferred (Right) language for person-first language.[128]

Intended audiences: All stakeholders may use person-first language **when** preferred by the participants with whom they are engaging. Person-first language can be considered for verbal, written, web and app-based, graphic, and illustrative forms of communication.

Problematic	Preferred
Handicapped person, the disabled.	Person/people with a disability.
Normal person, typical person.	Person/people without a disability.
A quadriplegic.	Person with quadriplegia.
The blind.	Person/people who are blind or have low vision.
Learning disabled.	Person/people with a learning disability.
Wheelchair-bound or confined to a wheelchair.	Person who uses a wheelchair.
Handicapped accessible parking, bathrooms, etc.	Accessible parking, bathrooms.
Person with a birth defect.	Person with a congenital disability.

Tool B.1.ii: Example of plain language- medication instruction sheet before and after

Description: Plain language is a clear and understandable way of communicating. The example below was provided by Merck & Co. to the MRCT Center and is on the MRCT Center's health literacy website.[129] It shows complex language (Left) that has been adapted to plain language (Right). Key principles of plain language include:

- Logical organization and flow of content so that the intended audience knows what to do first,
- Presenting only the most necessary information,
- Using common or everyday words (*see if you can spot words to still improve at right below),
- Using simple definitions (sometimes with illustrations and/or analogies), and
- Using the active voice.

Intended audiences: 1) For research teams to use as a guide in preparing recruitment, patient-facing materials (such as consent forms and instructions for research procedures), for communicating in-person, and for return of results, 2) For investigators, sites, and research organizations to use in community engagement, and 3) For publishers to consider, such as through plain language summaries or abstracts, to make academic publications more accessible.

Complex language

Injection Guide for Study Drug or Placebo
Panel A (Days 1-5) and Panel B (Days 6-10)

Instructions for Use

Study Drug or Placebo Injection

Each vial contains 1 mL of study drug or matching placebo. The volume removed from the vial determines the dose administered. The study staff will tell you how much to inject from each vial.

Important Information

- **Refrigerate kit box: Do Not Freeze.**
- **Vials should only be used one time.**
- **Only uncap the vials that you are preparing to inject.**
- **Only inject the volume instructed by study staff. Do not inject the entire contents of either vial.**
- **Always use a new site-provided syringe/needle for each injection.**

Step 1: Prepare Vials

- Remove 2 vials from the kit box and return kit box to the refrigerator.
- Allow vials to come to room temperature for at least 15 minutes.
- Vials should then be inverted a minimum of three times.
- Wash your hands with soap and water.

Step 2: Prepare Syringe

- Remove the cap from one of the vials and wipe the top of the vial with an alcohol swab.
- Open a new syringe and needle.
- By pulling back on the plunger, draw air into the syringe up to the mark of the volume to be injected and then slowly inject the air into the vial.
- Keep the needle in the vial and turn the vial upside down. Make sure that the needle tip is well below the surface of the liquid in the vial.
- With the tip of the needle in the liquid, pull slowly back on the plunger to get the right volume into the syringe.
- Check the syringe for air bubbles. If there are bubbles, hold both the vial and syringe in one hand, and tap the syringe with your other hand. The bubbles will float to the top. Push the bubbles back into the vial, then pull back to get the right volume of study drug/placebo.
- When there are no bubbles, take the syringe out of the vial. Put the syringe down carefully so the needle does not touch anything.

Step 3: Injection

- Clean an injection site that is about 2-3 inches away from your belly button on your abdomen with a new alcohol swab. Let dry thoroughly.
- Hold the syringe in the hand that you will use to inject study drug. Use the other hand to pinch a fold of skin at the cleaned injection site.
- Use the injection technique shown to you by the study staff.
- After the needle is inserted and while pinching the skin, pull the plunger back slightly. If no blood appears, steadily push the plunger all the way down until the study drug is injected. **Note:** If blood enters the syringe, remove the syringe, clean and prepare another spot on your abdomen and using the same syringe/needle, inject the product.
- Leave the syringe in place for about 6 seconds after injecting (the pinch may be released) and remove. After the needle is removed, you can apply light pressure with clean gauze or cotton ball but, do not rub the site.

Plain language

How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine

Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

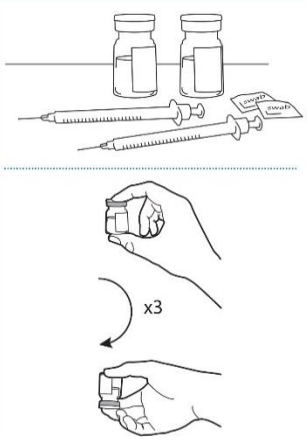
Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:
   - 2 syringes
   - 2 bottles of medicine
   - 2 alcohol swabs
2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
   - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
   - Turn the bottles upside down and then right side up at least 3 times.
3. Wash your hands with soap and water.



Tool B.2: Modification of the consent form for more inclusive use

Description: Clear communication is very important for all audiences. This is especially true when the information being communicated is necessary for people to make potentially life-altering decisions. Informed consent is a process by which individuals learn about and discuss the details of a research study before deciding whether to participate. The consent form is one part of the informed consent process. Consent forms that are overly complex do not empower individuals to make informed decisions about participation.

Provided below is an example of problematic language drawn from the privacy sections of three randomly selected consent forms on ClinicalTrials.gov (Left), and potential changes changed to engineer plain language communications (Right). To change the language:

1. Read through the problematic sentences and identify words or phrases that we may not be clear to some people reading the consent form. Such words and phrases include data, information, identifiable/de-identified, genomic, sequencing, deposited, publicly accessible, private, effective, entities, sponsors, accreditation, aligned, and domain.
2. Re-write the problematic sentences using plain language. See Tool B.1.ii: Example of plain language- medication instruction sheet before and after. Plain language principles include presenting only the most important information, using everyday words, using simple definitions, and using the active voice.
3. Break up the text by using shorter sentences and bullet points.
4. Run the re-written text through a health literacy editor[87] and edit further to make sure that all text is at an 8th grade reading level or below. Then hyperlink terms [where possible] to pages defining those terms in the MRCT Clinical Research Glossary[130].
5. Check to ensure that we used person-first language, where applicable, and that action words that may exclude some people with disabilities were modified. For example, instead of saying that individuals can “contact” someone for assistance, give different options for contacting that person (e.g., phone, email). Specifying that individuals “call”, “speak to”, or “write to” a person for assistance, or that individuals should “raise their hand,” should be avoided.
6. Make sure that it is clear that individuals can make use of accommodations when reviewing the consent form. The consent form should also clarify that individuals have a right to accommodations throughout the trial.

Finally, please note that this example of preferred language could be further improved with design formatting such as greater white space and pictures/icons illustrating concepts (see Tool B.3: Example patient portal website- potential challenges for people with disabilities). Although study tasks and participant payments are not shown in this example on privacy, such consent form sections may be further simplified through formatting and tables that break out the information.

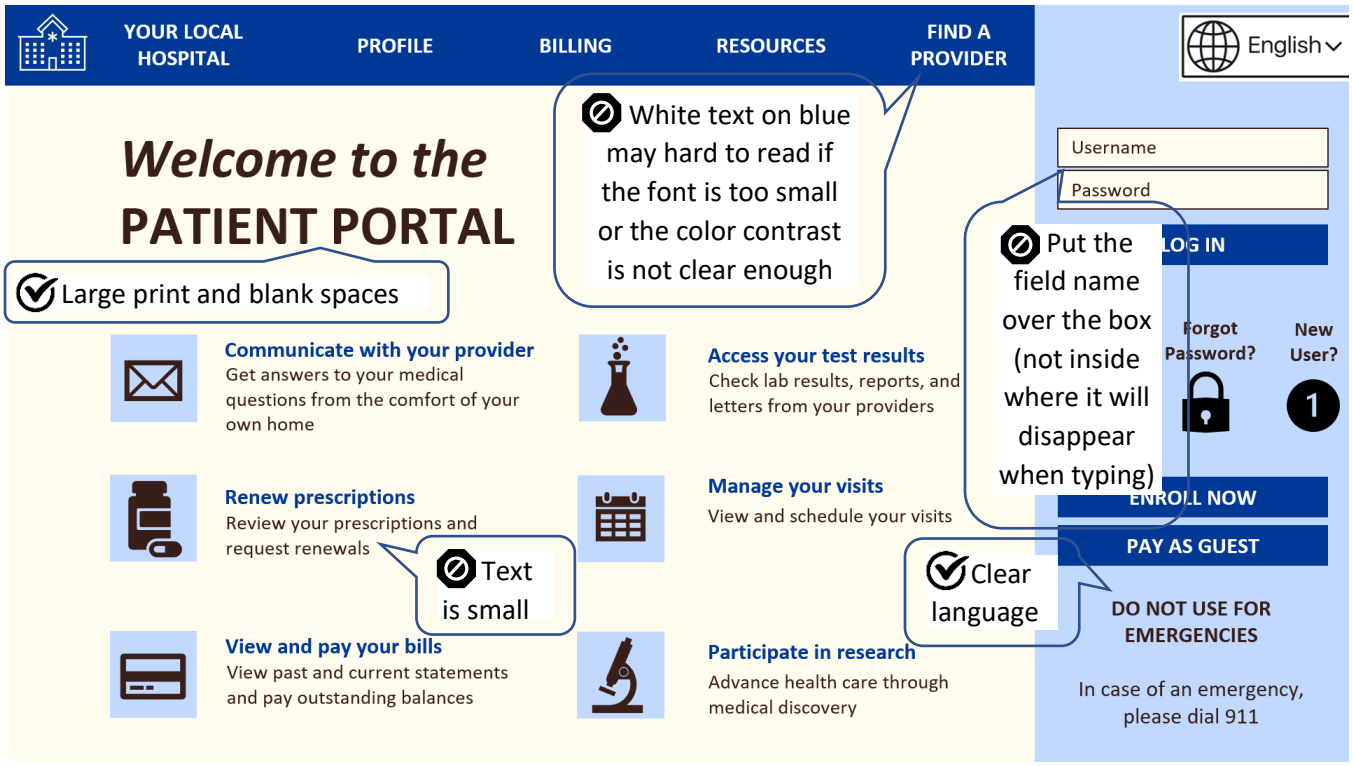
Intended audiences: 1) For research teams to use as a guide in preparing informed consent forms, 2) For IRBs to use as a guide in reviewing informed consent forms, and 3) For participants and patient advocacy groups to use in advocating for consent forms that are more informative.

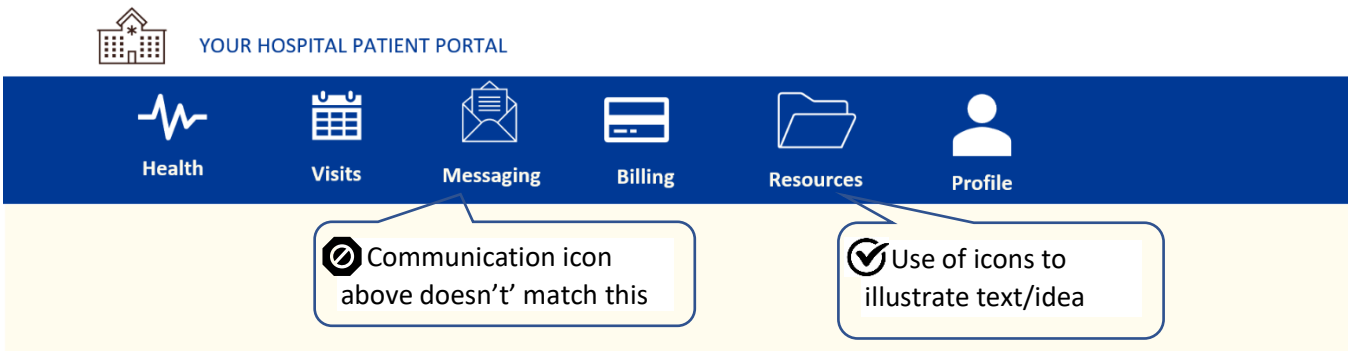
	Problematic language	Preferred language
Privacy	Throughout the course of this research, identifiable information (including your DNA sequencing or genomic data) about your health will be collected. De-identified genomic data generated in this study may be deposited in databases that will be publicly accessible via the Internet. People may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. Your health information is protected and considered private under federal law. In order for effective research to be performed, your data may be shared with the following entities: The sponsor(s) of this study, other researchers and medical centers that are part of this study and their ethics boards, entities that oversee the data and safety of this research, and organizations that provide independent accreditation and oversight of hospitals. All of the entities listed may not follow the privacy rules as outlined in this form, and there is a possibility that your health information may be used or shared without your permission in ways that are not aligned with our policy. Once your information is out of our domain, we cannot guarantee privacy.	During the research, we will write down 'data', or information, about you. Data can be: • Your name • Your birthday • Your height, weight, or other body measures • Things you have told your doctor or put on forms • Your test results (such as blood tests) • Your 'genomic' data, which is like a map inside the cells of your body that says who you are. The law says that we must keep your data safe and private. This means that: • We do our best to 'de-identify' your data. To do that we hide your name and use a code number for you. This means no one who looks at the data knows that it came from you. • We keep all your data that is on paper in a locked cabinet. We keep your data that is on a computer locked behind a secure password. • We only share your data with people working on the clinical trial that need it to do their jobs. Those people will have rules for keeping your data safe, but sometimes they are different than ours. Once your data is out of our hands, we can't promise it will stay private. • We don't use your name or data that says who you are when we write papers about the trial. For genomic data we can't hide that it is your data. Unlike your height or weight, no one else has the exact same genomic map. Right now, it would be hard to find you using your genomic data. But, in the future it might become easier to learn who you are. Please ask questions about being a study participant, and about the use of accommodations in the trial. You can contact [person] at [phone number/email]. You can work on this consent form with a friend or family member that helps you with making choices.

Tool B.3: Example patient portal website- potential challenges for people with disabilities

Description: One form of communication between medical teams and patients is the "patient portal," which is also used in clinical research. We provide a mock-up of a patient portal below and give a few examples in callouts below of both problematic (⊘) and helpful (✓) facets of the portal design that may affect accessibility. We recommend working with patient portal vendors that prioritize accessibility.

Intended audiences: 1) For research teams, research organizations, CROs, and sponsors to better understand what challenges participants may face using patient portals or web apps, to review portals and apps (especially as it can take significant time for tech support teams to make changes to web-based materials), and, where feasible, to prepare improved web-based materials; 2) For people with disabilities and allies to use in advocating for improved communication accessibility.





Tool C.1.i. Site assessment for inclusion of people with disabilities

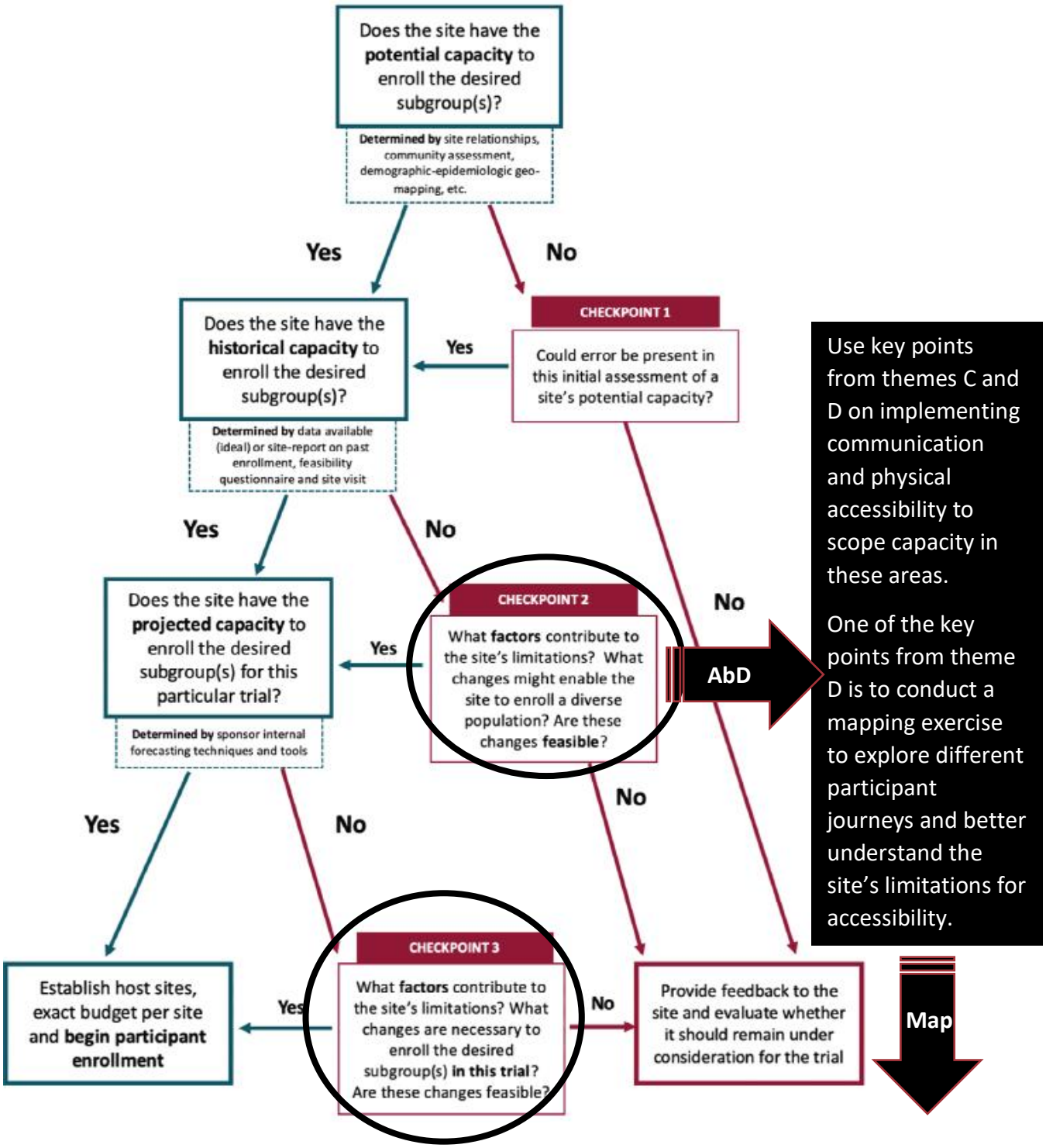
Description: The site selection process involves assessment of the potential, historical, and projected capacity of a site to fulfill the trial's goals for a representative population. Assessment of accessibility capacity should be a part of this process, and we illustrate below examples of this process:

Step 1: Review the circled sections in the illustration below, which is reproduced from the MRCT Center's Feasibility Decision Tree.[131] The circled sections are checkpoints where sponsor, CROs, and investigators assess the full scope of a site's limitations, inclusive of accessibility, and changes that may be necessary.

Step 2: Determine what to assess by using the key points from Themes C (communication accessibility) and D (physical accessibility). Map the participant journey to determine what changes may be needed for accessibility (see Tool C.1.ii. Map of the participant journey for people with disabilities-example).

Intended audiences: 1) For sponsors, CROs, and investigators to assess sites for physical accessibility. Please note, a professional service familiar with local laws (and preferably once inclusive of people with disabilities) may be helpful.

Tool C.1.i. Site assessment of limitations for inclusion of people with disabilities



Tool C.1.ii. Map of the participant journey for people with disabilities- example

Description: This tool should be used in combination with Tool C.1.i. Site assessment for inclusion of people with disabilities. A site assessment for physical accessibility requires a thorough understanding of the participant's (and family caregiver's or supporter's) journey starting from their home to transportation pick-up/drop-off, to the site location, getting into the site, navigating within the site to the different areas that they must access, interacting with different forms of medical equipment, and returning home. This perspective of this journey will be different for people with different disabilities. The examples below provide some ideas about the types of barriers individuals may encounter. Think about each stage of the journey for your study participants and brainstorm potential barriers.

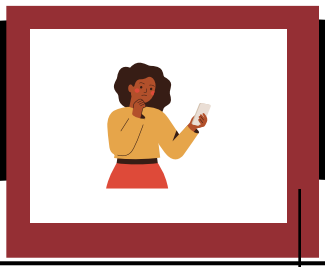
Use cases: 1) For sponsors, CROs, and investigators to assess sites for physical accessibility, 2) For research teams and patient navigators to better understand the experiences of people with disabilities and to anticipate accessibility needs, and 3) For human resource, procurement, and buildings/facilities departments to think through potential adaptations.

Tool C.1.ii. Map of the participant journey for people with disabilities- example

[As part of site assessment]

START

Navigate the site's online resources

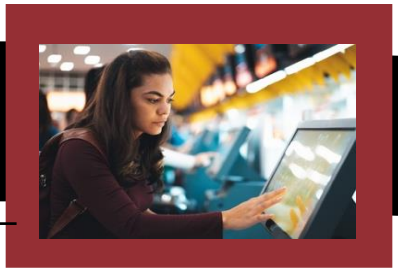


Information about where to go for study screening is on a pop-up picture. There are no written directions or Alt-text.

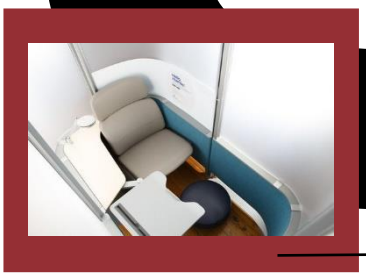
Get to the site

There is a wheelchair-accessible shuttle that stops a block from the site, but the sidewalks between the stop and the site are uneven.

Check-in when you arrive

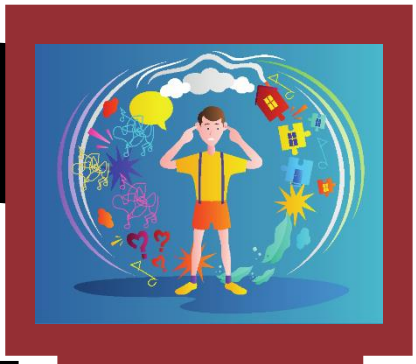


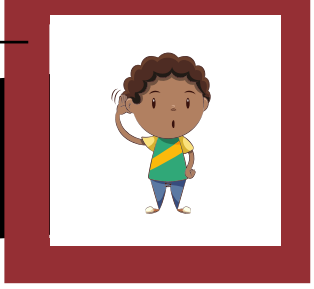
Check-in is through a touch-screen kiosk that does not have large font or braille and is not written in plain language.



The participant is a nursing mom, and the lactation pod space is not wide enough to maneuver a wheelchair.

Wait for research team to see you





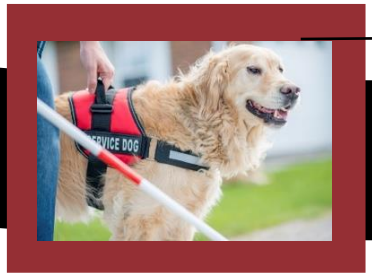
The waiting room is crowded and noisy, with a blinking overhead light. Announcements are only made verbally to admit each person.

Go to the exam room

The exam table height does not adjust, and it is difficult for the participant who uses a cane to get up onto the table.

The lab tests are in a mobile unit in a parking lot, surrounded by moving cars and hot pavement.

Get lab tests



FINISH

Tool D.1: Information brief for individuals asked to act as supporters for supported decision-making

Description: Just as information briefs are helpful for participants, so too are information briefs for people who are family caregivers or supporters for people with disabilities. Although it is common for participants to have a relative or friend accompany them to visits, the concept of supported decision-making in clinical research is less well-established. Both people with disabilities and supporters may not be fully aware of their rights and responsibilities. The information brief below provides a template for key points to convey to individuals asked to act as supporters.

Intended audiences: 1) For clinical trial stakeholders to post on their websites, 2) For healthcare providers to share with patients and supporters when discussing possibilities for participation in clinical trials, and 3) For investigators and their research teams to share with potential participants and supporters during the screening and consent processes.

Supported Decision-Making

A Guide for Supporting Clinical Trial Participants With Cognitive or Communication Challenges

People who take part in research are called **participants**. Supported decision-making is a strategy that lets participants choose **supporters** to assist them.

Supporters can be family members or friends. Others may be allowed, but it depends on the state law.

Supporters assist participants to learn more about the study and explain to researchers what they need and want.

Q: What Can I Do?

A supporter who is assisting with supported decision-making can:

- Discuss what actions might help the participant make decisions.
- Explain new things in easier ways for the participant, such as with stories or pictures.
- Work with the participant to think through the good and bad things about each option.
- Talk with the participant about their questions and concerns.
- Help access the participant's health, financial, school, and other information. You can do this without a special "ok" (permission) if that is the rule in your state.
- If the participant needs or wants you to, help the participant tell the research team about their questions and decisions. Check that the research team understands.

Q: Why Should I act as a Supporter?

- To help ensure that the research team knows the participant can make their own decisions.
- To help make sure that the participant is understood.
- To meet people like yourself who have been asked to help a person with 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 explains 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.

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?

Tool D.2: Legal, regulatory, and guidance related to supported decision-making

Description: Supported decision-making is a strategy that allows people to select trusted others to help them understand and communicate decisions. Importantly, supported decision-making is not substituted decision-making. The supporter is only a helper; the individual participant (designated in this tool as "individual principal" to reflect the use of the legal term "principal" in formal statutes) always remains the decision-maker. Help from the supporter may include reading information, explaining information, discussing how to work through whether to participate in a study, and communicating decisions. Supported decision-making may be used for many decisions, including economic transactions and health care, as specified in the arrangement. Entering a supported decision-making arrangement is fully voluntary, and individual principals retain the authority to revoke the support arrangement at any time.

The movement for supported decision-making was given impetus by the Convention on the Rights of Persons with Disabilities (UNCRPD),[20] which went into effect in 2008 and now has been ratified by 185 states parties [i.e., ratifying nations]. Article 12 of the UNCRPD provides that all persons with disabilities "have the right to recognition everywhere as persons before the law." States parties [i.e., ratifying nations] are to recognize that persons with disabilities are to "enjoy legal capacity on an equal basis with others in all aspects of life." States parties are, then, to "take appropriate measures to provide access by persons with disabilities to the support they may require" to exercise these capacities.

Although the U.S. has not ratified the UNCRPD, many U.S. states have now enacted supported decision-making statutes that align with the UNCRPD. Healthcare providers should be aware that these statutes, embodied in the law, create new rights and duties; in this respect, they are more than the informal use of support for patients that are commonly regarded as good medical practice. These statutes have many features in common but also vary in important ways.

To assist toolkit users with learning about supported decision-making statutes, we have created a tool with two parts:

- [D.2.i] A table synthesizing similarities and differences among available U.S.-supported decision-making statutes.
- [D.2.ii] A checklist of questions to ask participants about potential supported decision-making arrangements.

Intended Audiences:

- [D.2.i]: 1) For research chairs and IRBs to discuss with legal counsel when planning institutional policies on supported decision-making, 2) For research teams to ask legal counsel when planning studies, and 3) For participants and supporters to review with legal counsel in making supported decision-making arrangements.
- [D.2.ii]: 1) For research teams and treating physicians (if the treating physician is not the Principal Investigator) to ask participants and supporters prior to study entry.

Tool D.2.i: Features of available U.S.-supported decision-making statutes

	Similarities Across the United States	Differences/Nuances Across States
General	A supported decision-making arrangement is an additional legal tool that people have; it does not take away rights but gives additional rights and protections to both makers of the arrangement (individual principals and supporters) and to others who rely on the arrangement such as health care providers.	States differ about the relationship between supported decision-making arrangements and guardianship. Some states will only grant guardianship if there has been a finding that supported decision-making arrangements are not available. Some states permit supported decision-making arrangements to coexist with guardianship, but other states do not.
	Transactions entered into with support have the same legal status as transactions entered into without support.	States have different rules about what kinds of decisions may be included in the support arrangement.
	Some kind of formal process such as notarization is required for the creation of a supported decision-making arrangement.	The formalities for revoking an arrangement may differ. For example, some states require notarization of the revocation, but other states do not.
	Individual principals and supporters should have documents memorializing the arrangement. Third parties should request copies of these documents.	
Principal or Individual	Individual principals creating supported decision-making arrangements are presumed to have decision-making capacity; creating an arrangement does not provide evidence of incapacity.	
	Individual principals entering into a supported decision-making arrangement retain the legal authority to make their own decisions without consulting their supporter.	
	Supported decision-making arrangements must be fully voluntary and may be revoked by the individual principal at any time.	
Supporter	Supporters are not surrogates and may not act on behalf of the individual principal in the supported decision-making arrangement except as specified in the arrangement.	
	Supporters have the legal right to be present at and participate in decisions about care unless the individual principal of the arrangement requests otherwise.	

	Supporters have duties of fiduciaries to those they support, including obligations to keep information confidential and to only use information as requested by the individual principal.	States have different rules about whether supporters have access to relevant medical record information without HIPAA authorization.
	Supported decision-making arrangement are automatically terminated by substantiated allegations of abuse, if the supporter is convicted of a crime against an at-risk person or another crime causing physical harm, convicted of financial crime, convicted of theft; if there is a court-issued restraining order to protect the individual principal from the supporter.	States differ about who is qualified and disqualified as a supporter. Some states disqualify persons providing paid personal assistance services to the creator of the arrangement, persons providing formal health care services to the creator of the arrangements, or persons working for a government agency financially responsible for the care of the creator of the arrangement.
Third parties	Duties to report abuse continue unabated despite the existence of a supported decision-making arrangement. Persons with cause to believe that the supporter is abusing, neglecting, or exploiting the individual principal have duties to report the abuse.	
	Third parties such as health care providers are required to rely on the agreement and are not subject to criminal liability, civil liability, or professional misconduct for actions taken in good faith reliance on the agreement.	

Tool D.2.ii: Checklist of key considerations for specific supported decision-making arrangements

Step 1: Check to see whether your state has enacted a supported decision-making statute.

Step 2a: If your state **does** have a supported decision-making statute, proceed to the checklist below.

[Step 2a] Questions for research teams to ask participants and supporters about supported decision-making arrangements

- ☐ Would you like to have someone help you make decisions (a supporter)? Do you have a supported decision-making arrangement in place? If not, would you be interested in establishing a supported decision-making arrangement? [Make sure to clarify that this is fully voluntary and not a requirement for receiving care].
- ☐ Who is the supporter/s (if you already have one) or who would you like the supporter/s to be?
- ☐ What rights are given to the supporter/s in the supported decision-making arrangement?
- ☐ Are there any specific limits set out in the supported decision-making arrangement?
- ☐ Is there any reason to believe that the supported decision-making arrangement is no longer in effect (e.g., that it has been revoked, that guardianship has been granted, or that there have been substantiated allegations of abuse)?
- ☐ If you have a copy of the supported decision-making arrangement, may we have a copy?
- ☐ Do you have any other kind of relevant documents (e.g., a guardianship document)?

Step 2b: If your state **has not** enacted a statute, consider with your legislative liaison whether to support legislation for supported decision-making in your state. You may use the table in Tool D.2.i: Features of available U.S.-supported decision-making statutes to inform discussion with your legislative liaison. Please note, even if your state does not have a statue, research teams should still always ask participants if they would like a supporter to help them. Participants can still utilize supporters. They and their supporters ,as well as those with whom they interact, would just not be able to take advantage of the relevant supported decision-making statute, like the right to access health care records without HIPAA authorization (in some states). Proceed to the checklist below.

[Step 2b] Questions for research teams to ask participants and supporters about supported decision-making arrangements

- ☐ Would you like to have someone help you make decisions (a supporter)? [Make sure to clarify that this is fully voluntary and not a requirement for receiving care].
- ☐ Who is the supporter/s (if you already have one) or who would you like the supporter/s to be?
- ☐ May we share medical information with the supporter?
- ☐ Do you have any other kind of relevant documents (e.g., a guardianship document)?

Tool D.3 Positive signs that decision-making is supported (and not supplanted or substituted)

Description: In supported decision-making, a person with a disability can designate a supporter to assist with communication to and from the research team. Although the supporter may facilitate communication, and/or support the individual to make a choice by simplifying information and discussing pros and cons, the supporter is not the decision-maker. The tool below provides a list of positive signs that the participant is indeed the decision-maker.

Use cases: 1) For the investigator and their research team to assess if the supportive decision-making relationship remains supportive, 2) For IRBs reviewing study protocols to assess if the relationship being described as a supported decision-making arrangement maintains the participant's autonomy.

Positive support

- The supporter is respectful and listens to the participant and research staff.
- The supporter correctly interprets and "translates" communication between the participant and research staff.
- The supporter follows the lead the of participant in communicating a particular course of action and respects the decisions made by the participant. The supporter does not make decisions.
- The supporter (if also a family caregiver) continues providing requested assistance with daily life activities to a person with a disability independent of the research decisions that the participant makes.
- The supporter knows the participant's background, interests, regular behaviors, preferred ways of communicating, and likes and dislikes.
- The supporter respects, and may have assisted the participant in developing, a communication passport, which is a document owned by the participant that can help with communication in new situations.[132]
- The supporter can recognize if the participant becomes distressed.[133]
- [If the supporter completes study evaluations on behalf of the participant], the responses/opinions entered into the evaluations are those of the participant.
- The supporter does not express that they have a financial interest in whether the participant completes the trial.

Tool E.1: Example statements of commitment to inclusion of people with disabilities

Description: Public statements of commitment to the inclusion of diverse participant populations in clinical research drive accountability, define the mission and leadership focus, align operations with the mission, establish performance expectations, enable decision-making, and justify resource allocation.[134] They can reference specific populations, institutional priorities, short- and/or long-term goals, and human rights.

Intended audiences: 1) For sponsors, CROs, research centers, sites, and other organizations to communicate commitment to the inclusion of people with disabilities in clinical research, and 2) For people with disabilities and allies to advocate for disability rights and to hold stakeholders accountable.

Examples Statements of Commitment to Inclusion of People with Disabilities

- **Example 1: Valuable 500** [Manifesto excerpts].[135] Signatories include Bristol Myers Squibb, Deloitte, Eli Lilly, Johnson & Johnson, Merck, Microsoft, Pfizer, Roche, and Sanofi.
  - What we believe: [Excerpts] "One in, all in- We strive to be inclusive by design. That's why we only take part in events and experiences which are accessible to all; Actions, not words- In order to join the Valuable 500, the CEO or leader of each of our companies made a personal commitment to action for disability inclusion. This is what makes us different – we encourage our companies to take tangible action, not just talking about inclusion…."

- **Example 2: Harvard University Office for Equity, Diversity, Inclusion, and Belonging.**
  - Commitment statement:[136] "OEDIB views diversity, equity, inclusion, and belonging as the pathway to achieving inclusive excellence and fostering a campus culture where everyone can thrive. Our community is made of students, staff, faculty, and postdoctoral researchers who draw from a dynamic range of backgrounds to contribute to the pursuit of our common goals. The work and well-being of OEDIB are strengthened by the diversity of our network and our differences in background, culture, experience, national origin, religion, sexual orientation, gender, gender identity, gender expression, race, ethnicity, age, ability, political views, veteran status, and more. We actively seek and welcome people of color, women, persons with disabilities, people who identify as LGBTQIA, and those who are at the intersections of these identities, from across the spectrum of disciplines and methods to join us. Together, we strive to create an environment that values diversity, promotes an inclusive culture, and establishes a profound sense of belonging for each member of our community."

Acknowledgments

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- Matthew Dwyer, Directeur RSE (Corporate Social Responsibility), Co-Chair EnAble Employee Resource Group, Eli Lilly and Company
- Leslie P. Francis, Alfred C. Emery Professor of Law, Professor of Philosophy, and Adjunct Professor in Family and Preventive Medicine, Internal Medicine, and Political Science, University of Utah. *Author of AbD toolkit Tool D.II: “Legal, regulatory, and guidance elements of which to be aware for supported decision-making”
- Nora Groce, Professor, Cheshire Chair of Disability and Inclusive Development, and Director of the International Disability Research Centre, University College London
- Cecile González-Cerimele, Senior Director, Diversity & Inclusion in Clinical Trials, Eli Lilly and Company
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- Rebecca Langbein, Universal and Inclusive Design Consultant, Disability Solutions
- Katherine McDonald, Associate Dean of Research and Professor of Public Health, Falk College, Syracuse University; Chair, Institutional Review Board (IRB), Syracuse University
- Duke Morrow, Community Member, Institutional Review Board, University of Michigan
- Ari Ne’eman, PhD Candidate in Health Policy, Harvard University; Co-Founder of the Autistic Self-Advocacy Network
- Maya Sabatello, Associate Professor of Medical Sciences, and Co-Director, Precision Medicine: Ethics, Politics and Culture Project, Center for Precision Medicine and Genomics, Department of Medicine and Division of Ethics, Department of Medical Humanities and Ethics, Columbia University
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- Rachel Skoss, Senior Research Fellow, University of Notre Dame Australia; Past Chair of the Ministerial Advisory Council on Disability (WA)

- Michael Ashley Stein, Visiting Professor of Law, Harvard Law School; Co-founder and Executive Director of the Harvard Law School Project on Disability
- David H. Strauss, Associate Professor of Psychiatry, Columbia University Medical Center
- Courtney Wooden, Associate, EERP (MIH) Rotational Program (Design Hub Patient & Site Experience, Diversity, and Inclusion in Clinical Trials), Eli Lilly and Company

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