Brigham and Women's Hospital
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HARVARD MEDICAL SCHOOL

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

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Submitted February 7, 2024

Re: **RIN 1190–AA78**
Docket No. CRT 143 AG Order No. 5852-2024
Nondiscrimination on the Basis of Disability; Accessibility of Medical Diagnostic Equipment of State and Local Government Entities

To whom it may concern:

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) appreciates the opportunity to comment on the Department of Justice (DOJ) Notice for Proposed Rulemaking (NPRM) request to revise the regulations implementing title II of the Americans with Disabilities Act (ADA), 28 CFR part 35, in the draft, *"Nondiscrimination on the Basis of Disability; Accessibility of Medical Diagnostic Equipment of State and Local Government Entities,*" published in the Federal Register on January 12, 2024. It is a timely, welcome, and important proposed rule that seeks to further protect the civil rights of individuals with disabilities.

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor with the institutions with which its authors are affiliated.[1]

The MRCT Center applauds the DOJ's considerations of the rights of people with disabilities and their effort, in concert with the Department of Health and Human Services (HHS) through their proposed rulemaking to strengthen section 504 of the Rehabilitation Act of 1974, to clarify and strengthen the regulations implementing Title II of the ADA. We fully endorse the proposed Rule and offer comments only as they relate to our particular focus on clinical research and, in some instances, medical care. We offer these comments in strong support of the proposed Rule

[1] Brigham and Women's Hospital, Mass General Brigham, Harvard Medical School, and Harvard University.

and present some suggestions to further strengthen the Rule, in concert with the overall aim of the regulation.

1. Page 2185: The background text states, "A public entity must operate each service, program, or activity so that, when viewed in its entirety, the service, program, or activity is readily accessible to and usable by persons with disabilities, subject to a defense of fundamental alteration or undue burden." It would be helpful to clarify what "in its entirety" means in practice. An activity may be part of a program, service, or organization, yet it is essential to be accessible; it is unclear, therefore, at what level ("when viewed in its entirety") the accessibility standards must be met. We believe that if any component part of any service, program, or activity is necessary for that service, program, or activity, then it must be accessible and usable by persons by disabilities. Further, if resources and budget are used to claim "undue burden," the denominator for determining undue burden is the cost of the accommodation compared to the public entity or organization as a whole.

2. In addition (and as previously noted in the MRCT Center's Public Comments on the Proposed Rule for 504), it would be helpful to clarify to which medical equipment, sites of care, settings, and situations the proposed Rule would apply. This is particularly important in the context of decentralized trials, where diagnostics may be conducted remotely, in the home, or in settings like mobile units that often have small, confined spaces and limited options to move or adjust equipment. Would a stand-alone community clinic be expected to have available the full armamentarium of accessible medical diagnostic equipment (MDE)? Are the standards only for MDE at permanent sites (and of what size), or also for MDE used in decentralized care and trials? For example, would a visiting nurse attending a patient at home be expected to have an accessible scale? Do all FDA-approved and other devices (e.g., activity tracker bracelet, smartphone memory task mobile application, spirometer with smart connectivity) also need to be accessible? We are not challenging the spirit of the proposed Rule, which we endorse, but requesting further clarification of its reach and intention.

There are other logistical and practical questions that arise. If sites share equipment, e.g., an accessible MRI is accessible at a collaborating site, who is responsible for patient transport to that site? If a patient must travel to access that MDE, is insurance expected to provide coverage, and what if the patient has no or insufficient insurance? How far can that second site be, and what are the expectations for rural communities? OCR guidance to help frame solutions to these and many other questions would be helpful.

3. Page 2185: The technical requirements for MDE seem to be based on Access Board criteria that define entry, use, and exit of MDE by the patient by the "(1) supine, prone, or side-lying position; (2) seated position; (3) seated in a wheelchair; and (4) standing position." In combination with text throughout the proposed Rule that focuses only on

mobility disabilities, these criteria are concerning because they do not encompass people with disabilities beyond mobility impairment, such as people with sensory, intellectual, visual, hearing, or other disabilities. In some cases, the physical design or functioning of the equipment may not be usable for people with these types of disabilities, while in other cases adjustments to the environment, staff training or support, and communication with patients may be necessary to facilitate use.

4. Page 2187: The MRCT center strongly agrees with the statement, "A health care provider also cannot require a patient with a disability to bring someone along with them to help during an exam. A patient may choose to bring another person such as a friend, family member, or personal care aide to an appointment, but regardless, the health care provider may need to provide reasonable assistance to enable the patient to receive medical care." Family caregivers are often asked to provide care during medical appointments, such as transferring their loved one from a wheelchair to an exam table. This is not the responsibility of the family caregiver or person accompanying the patient. While a family caregiver may choose to assist, they should not be required or pressured to do so. The MRCT Center therefore suggests changing the second sentence above to be "A patient may choose to bring another person such as a friend, family member, or personal care aide to an appointment, but regardless, the health care provider ***shall*** provide reasonable assistance to enable the patient to receive medical care, ***unless declined by the patient***."

5. Page 2189: The text states, "Thus, this section does not require a public entity to acquire an accessible examination table and an accessible weight scale if doing so would result in a fundamental alteration in the nature of the service, program, or activity or in undue financial and administrative burdens, per § 35.211(e) and (f)." It would be helpful if the document could more clearly explain what constitutes undue financial or administrative burden. There are many types of facilities that conduct clinical research, from large and well-funded hospital systems to local clinics in underserved communities. The interpretation, therefore, of undue burden varies.

In addition, it would be most helpful if medical sites were required to post publicly on their website a clear statement about which of their diagnostic or other equipment are not accessible, and how they plan to make that diagnostic equipment accessible or otherwise accommodate people with disabilities. Such a statement could be part of a larger statement about other aspects of accessibility at that site (e.g., physical accessibility of spaces, accessibility of communication modalities like portals/apps).

6. Page 2190: The MRCT Center would welcome examples to help define what is meant in the following statement, "Here the proposed rule adopts an approach analogous to the concept of program accessibility in the existing regulation implementing title II of the ADA. Under this approach, public entities may make their services, programs, and activities available to individuals with disabilities without extensive retrofitting of their

existing buildings and facilities that predate the regulations, by offering access to those programs through alternative methods." What is meant by "analogous to the concept of program accessibility in the existing regulation implementing title II of the ADA." It would be helpful to give a more detailed synopsis of the approach in Title II, particularly when it is difficult for a facility to provide the recommended equipment. The following sentence states that alternative methods could be used. We recommend adding clear examples of the alternative approaches that have been used for different types of MDE in different contexts (e.g., low-resource settings, rural settings, varying types of disabilities).

7. Page 2190: The MRCT Center commends the DOJ for considering the financial impact on people with disabilities when they may need to access MDE in a facility that is not close to them because local facilities are unable to provide accessible MDE. The text states, "However, such an arrangement would not provide an equal opportunity to participate in or benefit from the service, program, or activity if it was, for example, significantly less convenient for the patient or if the visit to a different location resulted in higher costs for the patient." Will the proposed Rule offer guidance on reimbursing patients for travel costs, childcare, lost wages for time spent in transit, and other expenses if the person with a disability must travel farther to access diagnostic equipment than a person without a disability?

8. Page 2191: The text states that the "Department seeks public comment on whether this rule should apply to medical equipment that is not used for diagnostic purposes." We fully support the application of the Rule to all medical equipment, including preventative, therapeutic, and long term follow up. What justification could there be for not applying the Rule to equipment beyond that directly used for diagnostic purposes? All people have the right to be able to access medical equipment to support better health, whether that equipment is for diagnostic purposes or not. Further, even if we were to limit the scope to be for diagnostic purposes, durable equipment such as hospital gurneys need to be accessible for patients to be able to get to the location of diagnostic equipment like MRI machines. That is to say that even when diagnostic like MRIs are accessible, that equipment is useless if patients don't have accessible options to get to/into the medical site, through the exam room spaces, potentially onto stretchers or other equipment, and onto/into diagnostic equipment. All these components are interconnected. Further, the proposed Rule give the example of infusion chairs as equipment that is not used for diagnostic purposes. While that may be the case in large facilities and for specific types of infusions such as chemotherapy, an exam table or chair may be used for infusion purposes in smaller or mobile sites, or for infusions of shorter duration such as biologics or monoclonal antibodies. Exam tables and chairs are often used to support diagnostic screening. Therefore, the line between diagnostic and non-diagnostic equipment is a blurry one.

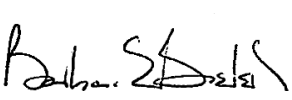
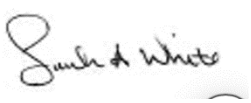
9. Page 2192: The MRCT center fully supports that, "The proposed Rule requires public entities to ensure that their staff are able to successfully operate accessible MDE, assist with transfers and positioning of individuals with disabilities, and carry out the program access obligation with respect to existing MDE." Both staff and training of that staff are critical to supporting the accessibility of MDE, whether with physical, communication, or social support to use the equipment.

10. The MRCT Center notes that the proposed Rule does not refer to remote diagnostic equipment, such as remote glucose, blood pressure, or blood oxygen monitoring, among others. We recommend including consideration for these remote technologies, and what the accessibility standards should be. If clinical research participants are required to utilize the diagnostic devices at home and input data into a computer, can participants with different disabilities do so? For example, do the device screens have options for larger font and are the written text and images formatted use with screen readers? Are there options for the instructions and other information to be in languages other than English? Is each page of the diagnostic tool application formatted for accessibility (and not only the first page)? Is technology support (e.g., online, phone) set up to be accessible? Can someone with limited mobility fit a blood pressure cuff or twist open the bottle for glucose test strips without assistance? Expectations for making all layers of a remote-use MDE product accessible, including the instructions and support necessary to use that product, should be mentioned in the final Rule.

We appreciate that the DOJ has embodied in this Rule extensive protections for the civil rights of people with disabilities, and our comments should be taken as complementary to the more expansive protections offered by the NPRM. We believe these few further clarifications would strengthen the Rule for the benefit of the health and safety of people with disabilities.

Please feel free to contact the MRCT Center (bbierer@bwh.harvard.edu, sawhite@bwh.harvard.edu, or wdecormierplosky@bwh.harvard.edu) if we can be helpful or you wish to discuss.

Respectfully submitted,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