Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD MEDICAL SCHOOL

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

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Submitted at http://www.regulations.gov by searching for
the Docket ID number HHS–OCR–2023–0013

November 11, 2023

Re: **Docket No. OCR-2023–0013**
Discrimination on the Basis of Disability in Health and Human Service Programs or Activities

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 Notice for Proposed Rulemaking (NPRM) request of the Office for Civil Rights (OCR) for comments on the draft, *"Discrimination on the Basis of Disability in Health and Human Service Programs or Activities,"* published in the Federal Register on September 14, 2023. 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 OCR's considerations of the rights of people with disabilities and OCR's effort to clarify and strengthen Section 504 of the Rehabilitation Act of 1973. We fully endorse the 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 support of the proposed Rule and present some suggestions to further strengthen the Rule, in concert with the overall aim of the regulation.

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

1. Page 63395: Section III is entitled, '*III. Nondiscrimination in Programs and Activities A. New Provisions Addressing Discrimination on the Basis of Disability Under Section 504 § 84.56 Medical Treatment'* implying that all information will relate to "Medical treatment." The document states that, " 'Medical treatment' is used in this section in a generic, nonspecific manner; it is intended to be broad and inclusive. It refers to the management and care of a patient to identify, address, treat, or ameliorate a physical or mental health condition, injury, disorder, or symptom, whether or not the condition constitutes a disability and whether the medical approach is preventive, curative, rehabilitative, or palliative." In this introductory section of Part III on Nondiscrimination in Program and Activities, it would be helpful to elaborate on other programs and activities in addition to medical treatment, to make it clear that activities such as clinical research are subject to the proposed rule. While clinical research participation is addressed, starting on page 63401, it is not clear from the table of contents or the introductory language at the outset of the document that clinical research (or other programs and activities) is covered.

2. Page 63398: We fully endorse that medical futility judgments should be made on a non-discriminatory basis. It is one thing (and acceptable) to say that a treatment is not effective for a specific condition and thus that treatment should not be given. It is quite another (and unacceptable) to say that, while the treatment is effective for a specific condition, it will not be given because of subjective quality of life judgments made by someone other than the patient or their legally authorized representative.

3. Page 63401: We agree that the evidence supports the conclusion that people with disabilities are often excluded from clinical research, and that "exclusion criteria [should] be written in a way that does not unnecessarily screen out people with disabilities whose research participation would not alter the intended purpose of the program of clinical research being undertaken." We would advise that the phrase "exclusion criteria" be changed to "eligibility criteria," which encompasses both inclusion and exclusion criteria. Statements in both the inclusion and exclusion criteria can serve to screen out people with disabilities. For example, a statement listed under inclusion criteria may say something like "Subjects with visual and auditory capacities sufficient to complete study surveys." A common inclusion criterion is "Participant is able to read, write, and communicate in English," a criterion problematic for many reasons.

   We also advise that eligibility criteria be written so that all criteria that can serve to screen out a participant are specific about the condition(s) that are excluded and that these criteria are accompanied by clear written justification of the medical, safety, or ethical reasons for exclusion. As referenced on pages 63402 (Glasgow Coma Scale) and 63410 (Expanded Disability Status Scale), the scales and instruments used to determine study eligibility, assess level of performance, or predict morbidity or mortality may discriminate against people with disabilities. In study protocols, these scales and

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instruments should be carefully considered so that people with disabilities are not unnecessarily screened out. For example, a threshold of the Eastern Cooperative Oncology Group (ECOG) performance scale is often used in the eligibility criteria of cancer studies and can set threshold scores of 0 or 1 for inclusion. However, the scale assigns a score of 1 or higher to anyone who is not "ambulatory," which may be interpreted to be any person who uses a wheelchair. In some cases, a scale or measurement method may be adapted to be more inclusive of people with disabilities, and, in other cases, a new scale or measurement method may need to be utilized or developed. This issue (and example) is relevant also to § 84.57 Value Assessment Methods (page 63409).

In addition to eligibility criteria, people with disabilities are often excluded because of their inability to complete an outcome assessment, when modifications to that assessment method can be reasonably made. Cardiovascular fitness can be measured by other means than a treadmill or a Fitbit. Sarcopenia and skeletal muscle mass may be assessed by tongue pressure rather than handgrip strength, and the use of video word recognition tests can be used to measure dementia in people who are deaf and use sign language. An important consideration is non-discrimination with respect to research procedures and study outcome measures for people with disabilities.

4. Page 63401: § 84.68(b) "prohibits the use of discriminatory methods of administration, criteria, and protocols, including discrimination in the allocation of scarce resources." This should include efforts to connect clinical trial participants to continuing care and, where possible, to continued access to study products (e.g., drugs, devices) at the conclusion of the trial. Such efforts and continued access to study products should not use methods in the allocation of scarce resources that discriminate against people with disabilities. In addition, all people with disabilities who continue with care and, as applicable, access to study products should be provided with the same accommodations and support to utilize these products that they received during the trial.

5. Page 63402: We fully support § 84.56(a) in that "no qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in medical treatment under any program or activity that receives Federal financial assistance, including in the allocation or withdrawal of any good, benefit, or service." For clarity, discrimination is impermissible if a person with a disability could benefit from a medical treatment relating either to the disability or a separately diagnosable condition. If someone without the disability would be offered the treatment, then that same treatment should be offered to the person with a disability, whether the condition itself is or is not related to the disability, or whether or not the condition itself would qualify as a disability. Withholding medical treatment must be justified on medical grounds that would apply to anyone—regardless of disability status—with the condition. Only if the underlying condition would likely impact the effectiveness of the "clinically appropriate treatment" would reasonable medical judgment include limiting or withholding treatment. This logic

applies equally to situations in which patients would be offered the opportunity to enroll in clinical research or a clinical trial.

6. Page 63404: The document states, "Proposed paragraph 84.56(b)(1)(i) confirms the prohibition against denying or limiting medical treatment based on bias or stereotypes. For example, refusing to provide a person with an Opioid Use Disorder (OUD) a referral for Medications for Opioid Use Disorder (MOUD) due to a provider's belief that persons with OUD will not adhere to treatment protocols would be prohibited under this paragraph." We fully support this prohibition against denying or limiting medical treatments based on bias or stereotype, and we applaud the use of the case study of discrimination against people who have a substance use disorder. People who use substances are often excluded in clinical trial protocol eligibility criteria without explanation and with little standardization as to how substance use is quantified (e.g., active use, use in the last 3 months, any historic use; use, abuse, addiction, dependence). The reasoning for these exclusions is unclear, although some protocols do mention that people (in general) will be excluded who are thought by study staff to be unable to complete the study reliably. The unproven belief by study staff that an individual is unlikely to complete the study is, in our opinion, biased and discriminatory.

2. Page 63407: "Section 84.56(c)(2)(i) makes clear that this section does not require a recipient to provide medical treatment to an individual where the individual, or the person legally authorized to make medical decisions on behalf of that individual, does not consent to that treatment." This is a helpful clarification. However, we caution all individuals should be offered the option of supported decision-making during the assessment of decisional capacity and the conduct of the consent process and, if able, to make an autonomous decision throughout the episode of care (or clinical research or study). This will help protect the rights and autonomous decision-making of the patient/participant and prevent withholding of treatment on the assumption that the patient/participant cannot or does not consent. As stated on page 63409, "The ability of a person with a disability or their authorized representative to understand the available options and to make an informed decision about the medical treatment depends in part on the expertise and candor of the treating professionals." This is partly true. Other components are whether the information is presented in an accessible way (e.g., in an appropriate sized font, in a format that can be read by screen readers, with sign language interpretation if information is given orally; in plain language; and in the preferred language of the individual) and if the participant is given the opportunity to bring a supporter that can help the patient/participant understand the information that they are being given and to help the patient/participant express their questions and preferences back to the provider.

3. Page 63409: We applaud the "the Department proposes to add § 84.57 on value assessment methods, indicating that a recipient shall not, directly or through contractual, licensing, or other arrangements, use any measure, assessment, or tool that discounts the

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value of life extension on the basis of disability to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available." One person's life is as valuable as another's, whether or not they have a disability.

4. Page 63449: We endorse the addition of a new subpart J to address the lack of accessible medical equipment for people with disabilities, the adoption of federal accessibility standards, and the adoption of the US Access Board's Standards for Accessible Medical Diagnostic Equipment (MDE Standards). It would be helpful to clarify which medical equipment, sites of care, settings, and situations to which the new subpart J would apply. For instance, would a stand-alone community clinic be expected to have available the full armamentarium of accessible equipment? Are the standards only for equipment at permanent sites (and of what size), or also for equipment 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? Do (or should) medical algorithms be developed and tested for appropriate prediction for people with disabilities, and how will that be monitored?

   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 someone has to travel, 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.

5. Page 63427: The update to the proposed rule on accessible communications and in particular, the attention to communication beyond print media such as web portals, apps, and social media, is welcome. We note that communication in languages other than English is not mentioned here and caution that communication in languages other than English should also be in accessible formats. Websites will often have a button that auto-generates text that has been translated into another language. But that text is not necessarily formatted to fit the page or text boxes on the page that were sized for English strings of text. Alt text descriptions of images are not routinely translated. The main page of a website is often rendered accessible but not the rest of the website nor its navigation. Tech support (e.g., online, phone) should also be set up to be accessible. Thus, expectations for making all layers of a communication product accessible, including the instructions and support necessary to use that product, should be mentioned in the final Rule.

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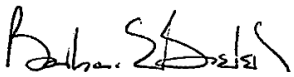
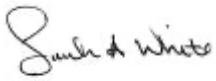
We appreciate that OCR has crafted this Rule with extensive protections for the civil rights of people with disabilities, and our comments should be taken as complementary to the more expansive protections offered by the NPRM. We believe these few further clarifications would strengthen the Rule for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