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

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Submitted July 15, 2024
To: *https:// www.regulations.gov/*

Re**:** **Document No. 2024-11838**
Federal Evidence Agenda on Disability Equity

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 White House Office of Science and Technology Policy (OSTP) Request for Information entitled, "*Federal Evidence Agenda on Disability Equity*," published at 89 Fed. Reg. 46924 (May 30, 2024) (the "Draft Guidance"). The topic is timely, welcome, and important to the public and will be critical to advance policy decisions for people with disability.

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] We focus here on information that would be helpful for the understanding of healthcare, health disparities, and clinical research. We limit our responses to the questions in the draft Guidance on data collection and participation barriers in clinical research and care, and we refrain from commenting on specific survey methodology used in federal and international data collection that is beyond our area of expertise.

The MRCT Center applauds the broader efforts from the White House and across the Department of Health and Human Services and other Departments to promote diversity and representation, and particularly the attention afforded people with disabilities. We offer the comments below to further the OSTP's efforts in supporting the Disability Data Interagency Working Group (DDIWG).

Comments

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

Introduction

The collection of reliable disability data remains a challenge to researchers, and we applaud the OSTP's commitment to measurements of health equity that is inclusive of people with disabilities. We share your vision for bringing disability data to the foreground and your enthusiasm for understanding where and how best to include questions on disability. People with disabilities are the largest minority population in the United States[2] and are designated by the National Institutes of Health as a population with health disparities. They are, importantly, a highly heterogeneous population, and this fact will impact data standards, collection, and analysis. Nevertheless, only with reliable data will we be able to inform meaningful policies, programs, and actions to address health disparities in clinical care and clinical research, among other areas. To that end, we would first like to thank OSTP for its commitment to this endeavor and its willingness to engage the public to provide input.

> *Identify practices for all Federal agencies engaging in disability data collection to follow in order to safeguard privacy, security, and civil rights, including with regard to appropriate and robust practices of consent for the collection of this data and restrictions on its use or transfer.*

For clinical research, there are standard practices to safeguard privacy and security, as outlined by federal policy (HIPAA, OHRP, FDA, DOD, NIH, and others) and implemented with institutional oversight. Clinical research teams should have a management plan for secure storage and transfer of data throughout the life cycle of the project, explicit data sharing policies, and defined timeframes for keeping the data and for deletion or disposition of the data at the conclusion of those timeframes. They should also have a plan in place for deleting data at a participant's request.

We recommend that research teams communicate clearly when, why, and how disability data will be collected and used. The data collection instruments should always include an option for participants to opt-out of answering any or all disability data questions, and it should be made clear in all participant-facing materials that this option may be exercised at any time during the research. Data and the data sources should be anonymized and/or de-identified if possible. Identifiable data should be retained only if necessary, and those data should be minimum necessary and fit-for-purpose. Disability data should be made available only through a controlled access environment, and research teams must consider which forms of data encryption would be the most appropriate.

With respect to informed consent, it is important to note that informed consent is a process that goes beyond whatever consent form is signed and acknowledged. The informed consent process should be frank, understandable (i.e., in plain language, logical information order, opportunity to

[2] Disability impacts all of us infographic. [Internet]. Centers for Disease Control and Prevention. [updated 2020 Sep 16; cited 2022 Oct 21]. Available from: https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html

go back/re-do sections), and in the preferred language of the prospective participant. Researchers are expected to provide reasonable accommodations for prospective participants who request or need them (e.g., large-print format, Braille, sign language, text-to-voice, supported decision-making, etc.).

What disparities faced by individuals with disabilities are not well-understood through existing Federal statistics and data collection?

There is very little information on disparities in participation in clinical trials because most trials do not yet collect data on disability status. The June 2024 proposed FDA guidance on Diversity Action Plans, which will be required for all phase 3 and later trials, does suggest collecting data on disability to better set recruitment goals that are reflective of the population who will use the investigational product, in their guidance focused on demographic diversity. However, the collection and reporting of disability data is a suggestion, while the collection and reporting of age, sex, race, and ethnicity data is required. Until disability data is collected, accurate information on disparities in disability participation and care and concrete plans for remedying such disparities cannot be devised.

Further, there is a lack of information on disparities in participation in the clinical research (and clinical care) workforce, which can include clinical care providers, researchers, and organizational leadership. We do not have basic information on representation and lived experience, nor do we have detailed information on equity in program graduation, e.g., medical school, residency, hiring, onboarding, mentoring, funding, and promotion rates. Such information is important not only to support equity for clinicians, researchers, clinical and research staff, and organizational leaders with disabilities, but also for patients and research participants who interact with staff in the clinical care and research settings. Just as for people who are underrepresented racial minorities or sexual and gender minorities, it is important for people with disabilities to be able to interact with staff who have disabilities and/or who have worked to better understand about anti-ableism, disability rights, universal design, and other foundational areas.

What barriers may individuals with disabilities face when participating in surveys or filling out administrative forms?

People with disabilities can face barriers participating in surveys when the surveys are not available in accessible formats (e.g., large font, Braille, audio-versions/sign language, screen reader-friendly formats with Alt Text for all pictures, plain language). Beyond the survey itself, there may be challenges if the software or web application to utilize the survey is not accessible. For example, a website may not follow the Web Content Accessibility Guideline (WCAG) or may do so only on main/initial pages of the website and not on more specific/internal pages. Or the portal or app may be accessible, but the instructions on how to access and use the portal or app, and the help desk associated with such portal or app, are not. If survey participants must

respond to questions in-person and the site is not physically accessible (e.g., no ramps, check-in kiosks that aren't height adjustable, or with audio-options), that also presents a barrier.

In addition, people with disabilities can't participate in surveys if they are not first asked. In clinical research, people with disabilities are often excluded before they can consider participating, because the study eligibility criteria list exclusions that prohibit their participation without any scientific, ethical, or safety justification.[3] For example, the eligibility criteria for a study involving a survey that is taken on a tablet or smartphone may exclude people with visual disabilities but does not state why. Perhaps it was assumed that people with visual disabilities are unable to complete the survey, the survey was not developed in an accessible format, and/or the research study would not allow for the use of accommodations (e.g., glasses, screen readers); none of which are valid reasons and are in fact forms of discrimination. In other cases, the eligibility criteria are so vague (e.g., "is judged by the investigator to be inappropriate for the study," "participant may confound study results," "participant is unlikely to complete the study")[3] that, without appropriate training, the staff considering the recruitment of potential study participants or survey respondents might inappropriately assume that potential (and otherwise eligible) participants with disabilities should not be asked to participate.

Which data disaggregated by disability are not currently collected by Federal agencies and would be useful and why?

It would be helpful to have data on disability that is disaggregated by age (including children categorized further as neonate, infant, child, adolescent), sex, race, ethnicity, sexual orientation, gender identity, and veteran status. Further, the type and severity of disability should be captured, as the understanding and implications of the resulting analyses will differ. People often have intersecting identities, but we do not have sufficient information or data available to understand these well either quantitatively or qualitatively. Improving health equity for people with disabilities, like improving health equity for any population, means seeing people for who they are and responding to their varied and complex needs.

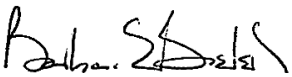
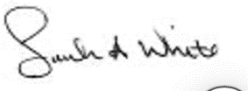
Conclusion

The MRCT Center is thankful for the opportunity to comment on this request for information. We reiterate our support for improving the representativeness – and thus, the overall quality – of data to inform meaningful policies, programs, and actions to address the health needs of people with disability, and we would welcome any opportunity to discuss.

[3] DeCormier Plosky W, Ne'eman A, Silverman BC, Strauss DH, Francis LP, Stein MA, et al. (2022). Excluding people with disabilities from clinical research: Eligibility criteria lack clarity and justification. [Internet]. Health Affairs, 41(10):1432-1432. [updated 2022 Oct 1; cited 2022 Oct 21]. Available from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00520

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 if you wish to discuss.

Respectfully submitted,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