

Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN)

Neuroethics Working Group (NEWG) Meeting

February 12, 2024

On February 12, 2024, the National Institutes of Health (NIH) *Brain Research Through Advancing Innovative Neurotechnologies®* (BRAIN) Initiative [Neuroethics Working Group \(NEWG\)](#) met virtually to hear presentations on potentially unique ethical considerations related to pediatric neurostimulation and emerging opportunities in neuroethics research, as well as updates from NEWG members.

[In opening remarks](#), Andrea Beckel-Mitchener, PhD, Deputy Director of the NIH BRAIN Initiative and Designated Federal Officer of NEWG, welcomed meeting participants. She thanked NEWG Co-Chairs Christine Grady, PhD, MSN, NIH Department of Bioethics, and Nita Farahany, JD, PhD, Duke University. John Ngai, PhD, Director of the NIH BRAIN Initiative, introduced two new NEWG members: Amy McGuire, JD, PhD, Baylor College of Medicine, and Jennifer French, MBA, Neurotech Network. He also highlighted two upcoming meetings: (1) a workshop on “Demystifying NIH BRAIN initiative Neuroethics Funding” during the [International Neuroethics Society 2024 conference](#) on April 17-19, 2024, and (2) the [10th Annual BRAIN Initiative Conference](#) on June 16-18, 2024. He also presented an active Notice of Special Interest ([NOT-OD-24-031](#)) to support research and capacity-building efforts related to bioethics. Recently released additional pair of BRAIN funding opportunities include: Research on the Ethical Implications of Advancements in Neurotechnology and Brain Science ([RFA-MH-25-170](#), R01 Clinical Trial Optional; and [RFA-MH-25-171](#), R21 Clinical Trial Optional). Dr. Ngai then highlighted a recent publication that provides guidance on ethical patient selection practices for neurostimulation clinical trials and suggests that deep brain stimulation (DBS) of specific thalamic regions can significantly improve cognitive function in patients with traumatic brain injury (TBI).¹

Theresa Cruz, PhD, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), and Christine Grady, PhD, NIH Department of Bioethics, introduced a panel of speakers to discuss potentially unique ethical considerations for pediatric neurostimulation trials. First, Adam Hartman, MD, National Institute of Neurological Disorders and Stroke (NINDS), set the stage by describing a pediatric case study and any considerations underlying the decision of whether the patient should be enrolled in a neurostimulation clinical trial. Next, Ben Wilfond, MD, Seattle Children’s Research Institute and University of Washington School of Medicine, presented ethical considerations for pediatric clinical trials, including improving the assent process to better engage pediatric patients in clinical research, as well as the importance of early and sustained community engagement. Martha Morrell, MD, Stanford University School of Medicine, discussed pediatric clinical trial design, including endpoints, considerations of medical urgency, use of extrapolation methods to translate findings from adult populations to inform trials on pediatric populations, and the importance of engaging patient advocates. Finally, Jenny Blumenthal-Barby, MD, Baylor College of Medicine, highlighted several recommendations for future work, including prioritizing the protection of vulnerable patient populations by encouraging their participation in clinical trials rather than excluding them, and addressing challenges related to cost

¹ Schiff, N.D., Giacino, J.T., Butson, C.R. et al. (2023). Thalamic deep brain stimulation in traumatic brain injury: a phase 1, randomized feasibility study. *Nature Medicine* 29, 3162–3174. <https://doi.org/10.1038/s41591-023-02638-4>

(e.g., traveling to clinic, post-trial care) and social support. During discussion, meeting participants emphasized the need to improve understanding of neuromodulation devices in younger populations through clinical trials and real-world data; they noted that funding incentives may help entice more researchers to facilitate research in this field. In addition, meeting participants underscored the importance of participant accommodations (e.g., providing transportation) in order to retain patients and remove barriers to participation. Meeting participants discussed extrapolation as an approach to use previous studies in adult populations to translate devices to younger populations; some participants recommended caution when extrapolating from studies of adult patients because not all aspects of a disease are the same in adult and pediatric populations. Meeting participants also expressed interest in allowing risk/benefit analyses to inform whether a trial should be initiated in younger populations and reconsidering the traditional approach of first testing devices in adults. A core theme of this session, while not necessarily unique to pediatric neurostimulation research, was to protect children through research, rather than from research. While most of the issues raised during the session may not be unique to pediatric neurostimulation research, the discussion raised unresolved issues that may warrant further exploration.

Dr. Farahany then introduced a panel on emerging opportunities in neuroethics research. First, Joseph Fins, MD, Weill Cornell Medicine, shared study findings that neuromodulation can restore a patient's personal identity that was altered following TBI. Dr. Fins emphasized the importance and value of personal identity, noting that the extent to which interventions can shift that sense of identity raises important ethical questions. Next, Alexander Huth, PhD, University of Texas at Austin, described approaches to decode language from functional magnetic resonance imaging (fMRI) data without the need for large training datasets. Although these advances could help support individuals with communication disorders, it will be important for researchers to address concerns about protecting patients' private information. Tristan McIntosh, PhD, Washington University in St. Louis, then presented on partnerships between academia and industry in neurotechnology research and the importance of ensuring that these partnerships align on key priorities, including intellectual property ownership, data transparency, patient safety, and informed consent processes. Meeting participants discussed how potential changes to personal identity should be addressed in neuromodulation clinical trials, how personal identity is more broadly impacted by serious illness, and how the nature of identity changes, as well as the potential risks and benefits, are likely interpreted differently by patients and family members. Meeting participants also highlighted the need to promote neuroethics resources, such as neuroethics liaisons to clinical trials.

Dr. Grady invited NEWG members to share relevant updates from their respective organizations. Caroline Montojo, PhD, Dana Foundation, shared the Dana Foundation's open call for submissions for [Neuroscience & Society pilot projects](#) and [2024-2025 Civic Science Fellow positions](#), as well as its partnership with the International Brain Research Organization and the Federation of Neuroscience Societies for Brain Awareness Week 2024. Next, Sameer Sheth, MD, PhD, Baylor College of Medicine, encouraged participants to attend the [American Society for Stereotactic and Functional Neurosurgery Biennial Meeting on June 1-4, 2024](#). Winston Chiong, MD, PhD, University of California, San Francisco shared that the American Academy of Neurology's Ethics, Law, and Humanities Committee will soon discuss bridging gaps between clinical practice and the neuroethics field. James Eberwine, PhD, University of Pennsylvania, discussed a [National Academy of Sciences, Engineering, and Medicine \(NASEM\) Working Group](#) focused on engaging scientists in southeast Asia with responsible innovation;

this effort will culminate in a series of workshops and a published report. L. Syd Johnson, PhD, SUNY Upstate Medical University, shared that she has authored two upcoming books: [*Philosophical, Medical, and Legal Controversies About Brain Death*](#) and a second book on research in nonhuman primates. Dr. McGuire is seeking to hire a [postdoctoral researcher interested in neuroethics](#). Jen French shared that the North American Spinal Cord Injury Consortium, in partnership with the University of British Columbia, recently published an article on data sharing,² and that Neuromodec and the American Brain Coalition are hosting a [webinar on neuromodulation and advocacy](#) on March 21, 2024. Dr. Farahany noted that the United Nations Educational, Scientific and Cultural Organization (UNESCO) has voted to support an effort focused on neurotechnology ethics, and encouraged NEWG members to attend an upcoming [NASEM workshop on neuroscience and artificial intelligence](#) on March 25-26, 2024.

The next NEWG meeting will be held on August 21, 2024, and a [videocast](#) will be available for live viewing and later archived.

² Warner, F. M., Tong, B., McDougall, J., Martin Ginis, K. A., Rabchevsky, A. G., Cragg, J. J., & Kramer, J. L. K. (2023). Perspectives on data sharing in persons with spinal cord injury. *Neurotrauma Reports*, 4(1), 781–789. <https://doi.org/10.1089/neur.2023.0035>