Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Neuroethics Working Group (NEWG) Meeting August 21, 2024

On August 21, 2024, the National Institutes of Health (NIH) *Brain Research Through Advancing Innovative Neurotechnologies*® (BRAIN) Initiative Neurotechnologies® (BRAIN) Initiative Ne

In opening remarks, Andrea Beckel-Mitchener, Ph.D., deputy director of the NIH BRAIN Initiative and designated federal official of NEWG, welcomed meeting participants. John Ngai, PhD, director of the BRAIN Initiative, then highlighted two previous meetings: (a) a workshop on "Demystifying NIH BRAIN initiative Neuroethics Funding" during the International Neuroethics Society (INS) 2024 conference and (b) the 10th Annual BRAIN Initiative Conference. He then previewed four upcoming events: (a) the University of Florida Health's Deep Brain Stimulation (DBS) Think Tank XII on August 21-23, 2024, (b) the Implantable Brain-Computer Interface Collaborative Community's (iBCI-CC) Inaugural Annual Meeting on September 18, 2024, (c) the Office of Human Research Protections' Exploratory Workshop on Human Research with Al on September 19, 2024, and (d) the U.S. Food and Drug Administration/NIH Workshop on Developing iBCI Clinical Outcome Assessments on September 19-20, 2024. Dr. Ngai highlighted a Notice of Special Interest (NOT-NS-24-073) focused on advancing research on ethical questions relevant to the National Institute of Neurological Disorders and Stroke (NINDS) mission, and a Request for Information (NOT-RM-24-011) on opportunities and challenges in advancing medical AI by integrating clinical imaging and multimodal data. Finally, he reviewed two recent publications, one that highlighted the concerns of patients with obsessive-compulsive disorder that DBS would create feelings of being controlled and that emotions were not their own,1 and another that outlined post-trial obligations in neural device trials based on the principle of moral entanglements.2

Next, Joseph Monaco, Ph.D., scientific program manager in the Office of the BRAIN Director, provided an overview of types of AI models, current applications for AI in neuroscience, and the limitations and ethical considerations of AI, including the intensive computational requirements, biases of training data, and potential skewed results of generative models. He concluded by highlighting a previous National Academies of Science, Engineering, and Medicine workshop on Exploring the Bidirectional Relationship between AI and Neuroscience, which had a session focused on regulatory and advocacy engagement, and two upcoming meetings: the 2025 INS Annual Meeting, focusing on Neuroethics at the Intersection of the Brain and AI, and the 2024 BRAIN NeuroAI Workshop occurring on November 12-13, 2024.

¹ Smith, J. N., Dorfman, N., Hurley, M., Cenolli, I., Kostick-Quenet, K., Storch, E. A., ... Blumenthal-Barby, J. (2024). Adolescent OCD patient and caregiver perspectives on identity, authenticity, and normalcy in potential deep brain stimulation treatment. Cambridge Quarterly of Healthcare Ethics, 1–14. doi:10.1017/S0963180124000203 ² Goering, S., Brown, A. I., & Klein, E. (2024). Brain pioneers and moral entanglement: An argument for post-trial responsibilities in neural-device trials. The Hastings Center *R*eport, 54(1), 24–33. doi:10.1002/hast.1566

Doris Tsao, Ph.D., University of California, Berkeley, described the components of common Al models, including convolution and transformer neural networks, and the necessary processes to improve Al models, including backpropagation, pre-training, and fine-tuning. Patrick Mineault, Ph.D., xcorr Consulting, then presented on foundational Al models in neuroscience, which can be pre-trained on electrophysiology or imaging data and further fine-tuned to identify clinical insights in drug efficiency, dementia risk, and psychological diagnosis, for example. Dr. Mineault also discussed ethical considerations related to Al such as how scaling up models can lead to inscrutability, fairness, data security and ownership, and equity of access to data, tools, and infrastructure.

Justin Baker, M.D., Ph.D., Harvard Medical School, and Ben Silverman, M.D., Mass General Brigham then introduced a case study on deep phenotyping in mental health and psychiatry. Dr. Baker described the use of multimodal measurements and latent construct models to assess mental health conditions and behaviors. Dr. Silverman highlighted critical ethical considerations for deep phenotyping in psychiatric research, including informed consent, privacy and confidentiality, equity, duty to warn or report, and the return of results to patients. Subsequent discussion focused on the following points: (a) informed consent is difficult for several reasons (e.g., participants may not fully understand what they are consenting to), (b) overprotection of study participants can lead to stigmatization, and (c) deciphering data ownership and responsibilities can be complicated (e.g., do researchers or the participants own the data?).

Next, Karim Jerbi, Ph.D., University of Montreal, and Debra Mathews, Ph.D., Johns Hopkins University, described the second case study on training large language models (LLMs) on brain data. Dr. Jerbi explained how to use neuroscience-generative pre-trained transformer (NeuroGPT), a foundational model that can improve electroencephalogram (EEG) classification performance and address challenges of data scarcity and heterogeneity in EEG data. Dr. Mathews presented on challenges and opportunities for research AI, as well as the <u>Blueprint for an AI Bill of Rights</u> and a recent report from the <u>Novel and Exceptional Technology and Research Advisory Committee</u>. Subsequent discussion focused on addressing bias within AI models and AI approaches that require less data than LLMs (e.g., small language models).

NEWG Co-Chair Nita Farahany, J.D., Ph.D., Duke University, invited participants to share thoughts on future directions for NEWG related to the AI case studies. Members suggested developing a commentary article, code of conduct, and best practices in the context of AI research, updating the Neuroethics Guiding Principles for research using AI, assessing current efforts throughout NIH related to AI, and determining how informed consent forms must be updated to enhance participant understanding of how their data will be used and accessed, privacy risks, and expectations (e.g., returning of data to participants).

Dr. Ngai invited NEWG members to share relevant updates from their respective organizations. Jen French, M.B.A., Neurotech Network, shared that the iBCI-CC launched and now has more than 200 active members. Caroline Montojo, Ph.D., Dana Foundation, noted that the Dana Foundation released a new story in the Neuroscience and Society series and noted that a second annual NeuroX Career Fair will be held on September 9-12, 2024. L. Syd Johnson, Ph.D., SUNY Upstate Medical University, shared that she has authored two books: *Philosophical, Medical, and Legal Controversies About Brain Death* and a second book on research in nonhuman primates. Karen Rommelfanger, Ph.D., Emory

University, shared that the Federation of European Neuroscience Societies recently hosted a neuroethics hackathon on neuroscience and Al scenarios and that her group is developing a strategy on participatory governance on neurotechnology for the European Union. Winston Chiong, M.D., Ph.D., University of California, San Francisco, shared that the American Academy of Neurology's Ethics, Law, and Humanities Committee will develop a neuroethics affinity group to plan a career event. NEWG Co-Chair Christine Grady, Ph.D., NIH Clinical Center, noted that she and Saskia Hendriks, M.D., NIH Clinical Center, were invited to contribute to a publication series in the *New England Journal of Medicine* focusing on ethics in innovative research. Dr. Farahany shared that she will attend the upcoming United Nations Educational, Scientific and Cultural Organization *Ad Hoc* Expert Group meeting to finalize a draft related to neurotechnology and neuroethics; she added that her group has finished the second iteration of the Applied Ethics + program and will publish a paper soon on legal considerations regarding neural data and cognitive biometrics.

For more on this August NEWG meeting, view the <u>video recording</u>. The next NEWG meeting will be held in May 2025.