Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN)

Neuroethics Working Group (NEWG) Meeting

August 28, 2023

On August 28, 2023, the National Institutes of Health (NIH) *Brain Research Through Advancing Innovative Neurotechnologies®* (BRAIN) Initiative Neuroethics Working Group (NEWG) met virtually to discuss a recent workshop on the ethics of data sharing and hear panel presentations on disclosure and participant control for sharing of individual-level human brain data.

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 James Eberwine, PhD, University of Pennsylvania Perelman School of Medicine, for serving as interim co-chair for this meeting. John Ngai, PhD, Director of the NIH BRAIN Initiative, thanked departing NEWG member Elba Serrano, PhD, for her service to NEWG, then provided an overview of recent BRAIN Initiative activities. In addition to providing a summary of the 9th Annual BRAIN Initiative Meeting, Dr. Ngai highlighted two recent workshops on Next Frontiers in Consciousness Research and Patient Recruitment in Deep Brain Stimulation (DBS) Clinical Trials. He also presented a recent *Neuron* article,[1] which summarized the findings from a 2022 NEWG workshop on continued responsibilities following clinical trials of implantable neural devices.

Next, Jay Churchill, PhD, Senior Advisor to the Director at the National Institute of Mental Health (*NIMH*) and Co-Lead of the BRAIN Neuroethics Program Team, presented an overview of the neuroethics research project grants that the BRAIN Initiative has supported since 2017. These projects have covered a broad array of neuroethical topics and many have engaged different stakeholder groups, including patients. The development of pragmatic dissemination plans in the form of, for example, enhanced neuroethics frameworks to inform decision aids and the development of best practices, have been at the heart of deliverables for these projects. The NEWG was then challenged to consider what potential future neuroethics research issues might be prime for BRAIN to consider. Meeting participants discussed the importance of funding emerging neuroethics topics (e.g., intersection of neuroscience and AI). They also noted the importance of encouraging applications that considered the development of the next generation of neuroethics researchers, careful consideration of stakeholder perspectives around data sharing (including cross-cultural perspectives), and of identifying opportunities to facilitate interactions between ethicists and scientists.

Saskia Hendriks, MD, PhD, Neuroethics Consultant at the National Institute of Neurological Disorders and Stroke (NINDS) and faculty in the NIH Bioethics Department, presented a summary of the recent NEWG workshop titled "Ethics of Sharing Individual Human Brain Data Collected in Biomedical Research." Dr. Hendriks explained that despite the benefits of data sharing, data sharing may come with potential risks to individuals, communities, and the research enterprise. Sharing brain data may be riskier than average biomedical data because of the sensitive inferences that may be drawn from the data, particularly in the future, potential information about stigmatized diseases, and re-identification risks of certain types of

[1] Hendriks, S., Hsu, N., Beckel-Mitchener, A. C., Ngai, J., & Grady, C. (2023). Continuing trial responsibilities for implantable neural devices. *Neuron*, S0896-6273(23)00541-X. doi:10.1016/j.neuron.2023.07.008

data. Uncertainty about future misuses of data can lead researchers and others to enact overly strict protections, which could affect capacity to reuse data, or overly lenient data sharing practices, which may increase risks. Dr. Hendriks noted that the risks of data sharing may exist on a spectrum on which datasets can be judged by the magnitude and likelihood of harm they could produce. The group discussed the importance of discovering what individuals and communities understand about how their brain data will be used and shared, and of learning from other scientific fields which kinds of data safeguards should be prioritized.

Next, Christine Grady, RN, PhD, Chief of the NIH Department of Bioethics and NEWG co-chair, introduced a panel on what information should be disclosed to study participants about the sharing and future use of their brain data during the informed consent process. Lucila Ohno-Machado, MD, PhD, MBA, from the Yale University School of Medicine, presented on iCONCUR, a consent management system that enables patients to decide with whom their data can be shared.[2] Most iCONCUR users want to share their data for research purposes, although this willingness depends on the data type. Dr. Ohno-Machado then discussed iAGREE, an experimental multi-institution blockchain-based consent management system in which patients can choose which data types they wish to share with specific studies. She noted that for some communities, group preference takes precedence over individual preference; as an example, a workshop was held with tribal leaders participating in the Strong Heart Study to determine community-sensitive approaches to soliciting data sharing preferences.[3]

Dr. Grady continued with a brief presentation on dynamic consent, which features personalized, online, and ongoing consent and communication among study participants, researchers, and data custodians. Dynamic consent enables greater participant control, engagement, and retention, but requires consistent communication and strong governance to be successful. Amy McGuire, JD, PhD, at the Baylor College of Medicine, then presented findings from a study of consent for data sharing in genetic research, with its implications for brain research.[4] In this study, study participants were randomly presented with one of three informed consent models and later interviewed about their data sharing decisions and preferences. The study found that participants preferred different consent options, whereas nearly all wanted to be involved in data sharing decisions. Dr. McGuire emphasized that research participants want to be treated with respect and to be able to trust the system. Respect and trust require the consent, security, and use of participants' data, and transparency and accountability from researchers.

Nita Farahany, JD, PhD, Duke University and NEWG co-chair, moderated NEWG roundtable updates, which included a Chilean court ruling in a case dealing with the protection of brain data, two Dana

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[2] Kim, J., Kim, H., Bell, E., Bath, T., Paul, P., Pham, A., Jiang, X., Zheng, K., & Ohno-Machado, L. (2019). Patient perspectives about decisions to share medical data and biospecimens for research. *JAMA Network Open*, *2*(8), e199550. doi:10.1001/jamanetworkopen.2019.9550

[3] Triplett, C., Fletcher, B. J., Taitingfong, R. I., Zhang, Y., Ali, T., Ohno-Machado, L., & Bloss, C. S. (2022). Codesigning a community-based participatory research project to assess tribal perspectives on privacy and health data sharing: A report from the Strong Heart Study. *Journal of the American Medical Informatics Association: JAMIA*, *29*(6), 1120–1127. https://doi.org/10.1093/jamia/ocac038

[4] McGuire, A. L., Oliver, J. M., Slashinski, M. J., Graves, J. L., Wang, T., Kelly, P. A., Fisher, W., Lau, C. C., Goss, J., Okcu, M., Treadwell-Deering, D., Goldman, A. M., Noebels, J. L., & Hilsenbeck, S. G. (2011). To share or not to share: A randomized trial of consent for data sharing in genome research. *Genetics in Medicine: Official Journal of the American College of Medical Genetics*, *13*(11), 948–955. doi: 10.1097/GIM.0b013e3182227589

Foundation [calls for proposals](), an upcoming [neuroscience and society virtual career fair](), and anticipated updates to the [Uniform Determination of Death Act](), including the neurologic criteria of death.

The next NEWG meeting will be held February 12, 2024, and a [video recording]() will be available for live viewing and later archived.