

**Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN)  
Neuroethics Working Group (NEWG) Meeting  
January 24<sup>th</sup>, 2022**

On January 24, 2022, the National Institutes of Health (NIH) *Brain Research Through Advancing Innovative Neurotechnologies®* (BRAIN) Initiative [Neuroethics Working Group \(NEWG\)](#) met virtually to discuss ethical challenges in implanted neural device research in humans.

[In opening remarks](#), Andrea Beckel-Mitchener, PhD, Designated Federal Official of the NEWG, thanked Khara Ramos, PhD, for her service as Director of the NIH Neuroethics Program. Next, John Ngai, PhD, Director of the NIH BRAIN Initiative, thanked Steve Hyman, MD, and Dr. Ramos for their service on and to the NEWG. Then, Dr. Ngai updated the group on BRAIN Initiative neuroethics activities. First, he reminded the group of the new data sharing policy ([NOT-MH-19-010](#)), which requires BRAIN-funded investigators to deposit their data into a BRAIN Initiative data archive. He also mentioned a request for information on the NIH genomic data sharing policy ([NOT-OD-22-029](#)), which welcomes public input through February 28, 2022. Dr. Ngai noted the availability of funds for administrative supplements to integrate ethicists into BRAIN-supported research (see [NOT-MH-22-040](#)). Lastly, he highlighted three recent BRAIN-funded scientific advancements in human neuroscience, including a [new deep brain stimulation \(DBS\) system](#) capable of wirelessly recording human brain data and adjusting stimulation levels in near real-time in people living with Parkinson's disease<sup>1</sup>. He also mentioned two breakthroughs in using DBS to treat and more precisely study psychiatric conditions, such as depression and OCD<sup>2,3</sup>.

Christine Grady, RN, PhD, Chief of the NIH Department of Bioethics and NEWG co-chair, introduced a session on ethical issues in implanted neural device research in humans. First, Ashley Feinsinger, PhD, bioethics faculty at the University of California, Los Angeles David Geffen School of Medicine, discussed [investigators' perspectives on ethical commitments, principle, and practices in implanted neural device research](#)<sup>4</sup>. In her talk, Dr. Feinsinger highlighted common types of basic intracranial human neuroscience studies and key ethical considerations, such as the unique context of this type of research, dual-role clinician-researchers, patient-participant vulnerabilities, and other issues. In light of these considerations, she walked the group through a proposed framework developed by investigators, which includes two overarching ethical commitments:

1. Maintaining the integrity of clinical care and space
2. Ensuring voluntariness of participation

Dr. Feinsinger discussed several principles and shared practices that align with each commitment. She noted that to ensure the integrity of clinical care, clinical care and research should be uncoupled, and that research design and protocols should honor this separation. In practice, this might involve clear communication with patients and making sure that they comprehend this distinction via verbal confirmation. To ensure voluntariness of participation, she explained that informed consent should be designed to account for neurological injury, a high rate of clinician-investigators, and patient population vulnerability. In practice, she recommended the use of standardized videos with external perspectives to

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<sup>1</sup> Gilron, R. E., Little, S., Perrone, R., Wilt, R., de Hemptinne, C., Yaroshinsky, M. S., ... & Starr, P. A. (2021). Long-term wireless streaming of neural recordings for circuit discovery and adaptive stimulation in individuals with Parkinson's disease. *Nature biotechnology*, 39(9), 1078-1085.

<sup>2</sup> Scangos, K. W., Khambhati, A. N., Daly, P. M., Makhoul, G. S., Sugrue, L. P., Zamanian, H., ... & Chang, E. F. (2021). Closed-loop neuromodulation in an individual with treatment-resistant depression. *Nature medicine*, 27(10), 1696-1700.

<sup>3</sup> Provenza, N. R., Sheth, S. A., Dastin-van Rijn, E. M., Mathura, R. K., Ding, Y., Vogt, G. S., Avendano-Ortega, M., Ramakrishnan, N., Peled, N., Gelin, L., Xing, D., Jeni, L. A., Ertugrul, I. O., Barrios-Anderson, A., Matteson, E., Wiese, A. D., Xu, J., Viswanathan, A., Harrison, M. T., Bijanki, K. R., ... Borton, D. A. (2021). Long-term ecological assessment of intracranial electrophysiology synchronized to behavioral markers in obsessive-compulsive disorder. *Nature medicine*, 27(12), 2154-2164.

<sup>4</sup> Feinsinger, A., Pouratian, N., Ebadi, H., Adolphs, R., Andersen, R., Beauchamp, M. S., ... & NIH Research Opportunities in Humans Consortium. (2022). Ethical commitments, principles, and practices guiding intracranial neuroscientific research in humans. *Neuron*, 110(2), 188-194.

supplement nuanced discussions with patients. Lastly, Dr. Feinsinger emphasized the unique features of this research space, including duality or dual-role researchers and the need for patient-participant input in the process. The NEWG briefly discussed ways to create standardized videos and how to integrate patient perspectives into research design. Next, Dr. Sara Goering, PhD, philosophy faculty at the University of Washington, overviewed ethical considerations for BRAIN research participation in long-term, highly interactive studies. Dr. Goering summarized her ongoing work on potential ethical concerns about human agency in people with brain computer interface (BCI) implants. She highlighted key features of these studies, such as the fact that BCI can both enhance and disrupt patient-participant agency, and that study participation is often perceived as time-consuming, exhausting, and risky. To demonstrate this, Dr. Goering shared several quotes from research participants with the group.

Dr. Grady led a panel discussion about key themes and ethical considerations in this research space. The panel was composed of Dr. Feinsinger, Dr. Goering, Dr. Kareem Zaghloul (an NINDS clinician-investigator), and Mr. James Johnson (a patient-participant with a neural implant). The NEWG considered ways to recognize participants for their rich contributions to research studies, such as acknowledging them as part of the whole research team. The group also discussed the importance of communicating clearly with patients, especially when explaining aspects of compensation, recognition, and individuals' roles within the broader research ecosystem. The NEWG discussed distinguishing ethical concerns in different research settings; for instance, "opportunity studies" that are usually short-term and happen during a clinically indicated surgical procedure versus long-term studies. The NEWG suggested ongoing consent processes and having a neutral individual (i.e., someone who is neither a researcher nor clinician) check in regularly with participants. The NEWG also noted the importance of connecting patient-participants with one another and the value of hearing patient stories, especially during long-term studies.

Dr. Grady concluded the panel discussion by summarizing key themes. She highlighted the distinction between "opportunity studies" and long-term studies, but also noted commonalities across all types of implanted neural device research, including ensuring clear and ongoing communication with patients and caregivers, and again, patient-participant recognition. Dr. Grady also mentioned trust, post-trial obligations, and other important ethical issues to keep in mind. Dr. John Ngai emphasized the importance of empirical research in understanding problems and how to move forward, and the power of including both investigators and participants in formulating new frameworks, guidelines, and best practices for conducting ethical research.

Dr. Hank Greely, Deane F. and Kate Edelman Johnson Professor of Law at Stanford University, and NEWG co-chair, then moderated a discussion focusing on NEWG goals for 2022 and beyond. NEWG members raised several potential ideas for consideration into future activities, including revisiting ideas raised in the [BRAIN 2.0 Neuroethics report](#). Additional ideas included: continued community outreach and patient engagement; issues in the non-medical prediction space; areas of intersection with neuroethics, genetics, and artificial intelligence; collaborations with other organizations that have ongoing neuroethics efforts; considerations of the broader, international neuroethics landscape; and issues on data sharing. In concluding remarks, Dr. Ngai highlighted potential issues of agency, data use and privacy, and challenges in equity and access as areas for the NEWG to consider. He emphasized clarifying the scope of NEWG input to BRAIN, which could have downstream impacts on the broader scientific community.

The next NEWG meeting will be held on Tuesday, August 23, 2022, and a [videocast](#) will be available for live viewing and later archived.