***Brain Research Through Advancing Innovative Neurotechnologies®* (BRAIN)**
Neuroethics Working Group (NEWG) Meeting
August 23rd, 2022

On August 23, 2022, the National Institutes of Health (NIH) *Brain Research Through Advancing Innovative Neurotechnologies®* (BRAIN) Initiative Neuroethics Working Group (NEWG) met virtually to discuss neuroscience and society, emerging ethics themes, and a recent workshop on continuing trial responsibilities.

In opening remarks, Andrea Beckel-Mitchener, PhD, designated federal official of the NEWG and deputy director of the NIH BRAIN Initiative, welcomed everyone to the meeting. Next, John Ngai, PhD, director of the NIH BRAIN Initiative, thanked Hank Greely, JD, NEWG co-chair, for his service as co-chair of the NEWG and welcomed Nita Farahany, JD, PhD, as incoming co-chair. He also welcomed Caroline Montojo, PhD, president and CEO of the Dana Foundation, as a new NEWG member. Dr. Ngai updated the group on a recent neuroethics workshop on continuing trial responsibilities and neuroethics-focused sessions at the 8th Annual BRAIN Initiative Meeting. He also highlighted two recent congressional neuroscience caucus briefings, which focused on the importance of brain donation and neuroethics.

Next, Dr. Montojo gave a presentation about the Dana Foundation's efforts to advance neuroscience and society. She described a recent cultural shift within the neuroscience community toward integrating neuroethics into neuroscience research, and the drivers behind this shift, including the Global Neuroethics Summit and other international brain initiatives. Next, she noted the importance of bidirectional public engagement in advancing science and policy and summarized a framework for successful public engagement[1]. The mission of the Dana Foundation is to advance neuroscience that benefits society and reflects the aspirations of all people. Dr. Montojo discussed three new programs in support of the mission: Dana Education, Dana NextGen, and Dana Frontiers. Lastly, she talked about several grant opportunities for brain awareness and education and establishing centers for neuroscience and society. Meeting participants noted the importance of getting more neuroscientists to recognize and value neuroethics. They also discussed the role of the foundation as a potential catalyst for change, especially in neuroscience, artificial intelligence, and other interdisciplinary fields of science.

Saskia Hendriks, MD, PhD, neuroethics consultant at the National Institute of Neurological Disorders and Stroke (NINDS) and faculty in the NIH Bioethics Department, presented findings from a portfolio scan of BRAIN grants awarded in fiscal year 2021. Based on reviewing publicly available abstracts, Dr. Hendriks and her colleagues identified 93/221 (42%) grants that may raise ethical challenges. NEWG members reviewed the abstracts from these grants and commented on the potential ethical challenges. Based on their comments, there were 10 neuroethics themes of interest. Each theme fell into one of two categories: 1) conducting research ethically; and 2) implications of research and new tools on individuals, groups, and society. In the first category, issues concerning general human subjects challenges and animal research ethics were raised most frequently. In the second category, improved human brain modulation and future non-clinical applications were most prevalent topics. NEWG members recognized the value in identifying opportunities for further neuroethical analysis. They also suggested paying closer attention to how ethics themes arising from BRAIN grants change over time. The group also considered ways to keep investigators better informed about emergent ethical themes that BRAIN may be interested in funding.

[1] Scheufele, D. A., Krause, N. M., Freiling, I., & Brossard, D. (2021). What we know about effective public engagement on CRISPR and beyond. *Proceedings of the National Academy of Sciences*, *118*(22), e2004835117.

Nina Hsu, PhD, science committee specialist at NINDS and interim co-lead of the BRAIN Neuroethics Program, summarized a recent workshop on continuing trial responsibilities. Built upon an earlier workshop in which the findings were then summarized and expanded in a subsequent publication, this workshop aimed to identify reasonable expectations for research-related care plans after the end of implanted neural device trials that could inform best practices for the research community. Dr. Hsu first provided examples of several potential research-related care needs for participants who keep using a device after a trial has ended, such as device maintenance and explantation. Panel discussions focused on four key themes: post-trial research-related needs, current practices, the minimum level of care that should be provided, and how to fill gaps between what is currently facilitated and what is sufficient. She also mentioned four conclusions:

1. Duration and extent of post-trial care may last a lifetime.
2. Some post-trial needs are covered, but many post-trial needs are not covered or are inconsistently covered.
3. While there are no perfect solutions and no way to plan for every scenario, we must do more to support participants and caregivers.
4. There may be limitations in resources and organizational mission scope, but professional stakeholders can collaborate to collectively facilitate post-trial care for participants.

The NEWG was fortunate to have a variety of individuals participate in the workshop, including bioethicists, researchers, device manufacturers, representatives from federal agencies, insurers, NIH staff, patients, caregivers, and many others. Lastly, Dr. Hsu talked about next steps, such as using a data-driven approach to better understand the post-trial care landscape and facilitating cross-stakeholder collaborations. The group discussed ways to improve informed consent, how post-trial needs impact both patients and caregivers, and notable issues beyond access to post-trial care (*e.g.*, the value of researcher-patient relationships, as well as coordination of care after the trial ends).

Lastly, Dr. Greely moderated a NEWG roundtable update session, during which members mentioned the upcoming Geneva Science and Diplomacy Anticipation Summit, the recent deep brain stimulation (DBS) think tank meeting, and a recent BRAIN-funded study in *Nature* on an organ perfusion system called OrganEx[2]. The next NEWG meeting will be held on January 24, 2023, and a videocast will be available for live viewing and later archived.

[2] Andrijevic, D., Vrselja, Z., Lysyy, T., Zhang, S., Skarica, M., Spajic, A., ... & Sestan, N. (2022). Cellular recovery after prolonged warm ischaemia of the whole body. *Nature*, *608*(7922), 405-412.